

RULE REVIEW ANALYSIS

Introduction: THIS RULE REVIEW IS SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED REVIEW

Short Title: Services Provided by Pharmacies

Rule Number: Chapter 291, Subchapter G (§§291.120-291.121, 291.123, 291.125, 291.127, 291.129, 291.131, 291.133)

Statutory Authority: Government Code, §2001.039, added by Acts 1999, 76th Legislature, Chapter 1499, Article 1, Section 1.11.

Background: Review of these sections follow the Board's rule review plan.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES

5
6 **§291.120 General**
7

8 (a) Purpose. This subchapter applies to all classes of pharmacies except as otherwise noted.
9

10 (b) Definitions.

11
12 (1) The Texas Pharmacy Act or Act--Subtitle J, other than Chapter 567, Occupations Code, as
13 amended.

14
15 (2) Board--The Texas State Board of Pharmacy.
16
17

18 **§291.121 Remote Pharmacy Services**
19

20 (a) Remote pharmacy services using automated pharmacy systems.

21
22 (1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy
23 services by a Class A or Class C pharmacy in a facility that is not at the same location as the
24 Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109
25 of the Texas Pharmacy Act.
26

27 (2) Definitions. The following words and terms, when used in this section, shall have the
28 following meanings, unless the context clearly indicates otherwise. All other words and terms
29 shall have the meanings defined in the Act.
30

31 (A) Automated pharmacy system--A mechanical system that dispenses prescription drugs
32 and maintains related transaction information.
33

34 (B) Remote site--A facility not located at the same location as a Class A or Class C
35 pharmacy, at which remote pharmacy services are provided using an automated pharmacy
36 dispensing system.
37

38 (C) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
39 manufacturer's original commercial container, or quantities of unit dosed drugs, into another
40 cartridge or container for dispensing by a pharmacist using an automated pharmacy system.
41

42 (D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy
43 (Class C) providing remote pharmacy services.
44

45 (E) Remote pharmacy service--The provision of pharmacy services, including the storage and
46 dispensing of prescription drugs, in remote sites.
47

48 (F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a
49 particular patient, by the prescribed route at the prescribed time, and properly labeled with
50 name, strength, and expiration date of the drug.
51

52 (3) General requirements.
53

54 (A) A provider pharmacy may provide remote pharmacy services using an automated
55 pharmacy system to a jail or prison operated by or for the State of Texas, a jail or prison
56 operated by local government or a healthcare facility regulated under Chapter 142, 242, 247, or
57 252, Health and Safety Code, provided drugs are administered by a licensed healthcare
58 professional working in the jail, prison, or healthcare facility.
59

60 (B) A provider pharmacy may only provide remote pharmacy services using an automated
61 pharmacy system to inpatients of the remote site.
62

63 (C) A provider pharmacy may provide remote pharmacy services at more than one remote
64 site.
65

66 (D) Before providing remote pharmacy services, the automated pharmacy system at the
67 remote site must be tested by the provider pharmacy and found to dispense accurately. The
68 provider pharmacy shall make the results of such testing available to the board upon request.
69

70 (E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required
71 to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel,
72 Operational Standards, and Records for Class A (Community) Pharmacies) and this section.
73

74 (F) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy
75 operations involving the automated pharmacy system located at the remote site including
76 supervision of the automated pharmacy system and compliance with this section.
77

78 (G) A pharmacist from the provider pharmacy shall be accessible at all times to respond to
79 patient's or other health professionals' questions and needs pertaining to drugs dispensed
80 through the use of the automated pharmacy system. Such access may be through a 24 hour
81 pager service or telephone which is answered 24 hours a day.
82

83 (4) Operational standards.
84

85 (A) Application for permission to provide pharmacy services using an automated pharmacy
86 system.
87

88 (i) A Class A or Class C Pharmacy shall make application to the board to provide remote
89 pharmacy services using an automated pharmacy system. The application shall contain an
90 affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or
91 the person responsible for the on-site operation of the facility (e.g., administrator, chief operating
92 officer, owner, chief executive officer), and include the following:
93

94 (I) the name, address, and license number of the provider pharmacy;
95

96 (II) name and address of the facility where the remote pharmacy services will be provided;
97

98 (III) a statement indicating that the provider pharmacy and the facility have entered into a
99 written contract or agreement which outlines the services to be provided and the responsibilities
100 and accountabilities of each party in fulfilling the terms of the contract or agreement in
101 compliance with federal and state laws and regulations; and
102

103 (IV) documentation that the automated pharmacy system is located where medications are
104 administered by license healthcare professionals and is:

105
106 (-a-) a facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code; or

107
108 (-b-) a jail or prison, operated by the State of Texas or local government.

109
110 (ii) Such application shall be resubmitted every two years in conjunction with the application
111 for renewal of the provider pharmacy's license. The renewal petition shall contain the
112 documentation required in clause (i) of this subparagraph except the notarized signature of the
113 medical director or the person responsible for the on-site operation of the facility (e.g.,
114 administrator, chief operating officer, owner, chief executive officer) is not required.

115
116 (iii) Upon approval of the application, the provider pharmacy will be sent a certificate which
117 must be displayed at the remote site.

118
119 (B) Notification requirements.

120
121 (i) A provider pharmacy shall notify the board in writing within ten days of a change of
122 location, discontinuance of service, or closure of:

123
124 (I) a remote site where an automated pharmacy system is operated by the pharmacy; or

125
126 (II) a remote pharmacy service at a remote site.

127
128 (ii) A provider pharmacy shall comply with appropriate federal and state controlled
129 substance registrations for each remote site if controlled substances are maintained within an
130 automated pharmacy system at the facility.

131
132 (C) Environment/Security.

133
134 (i) A provider pharmacy shall only store drugs at a remote site within an automated
135 pharmacy system which is locked by key, combination or other mechanical or electronic means
136 so as to prohibit access by unauthorized personnel.

137
138 (ii) An automated pharmacy system shall be under the continuous supervision of a provider
139 pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be
140 physically present at the site of the automated pharmacy system if the system is supervised
141 electronically by a pharmacist.

142
143 (iii) Automated pharmacy systems shall have adequate security and procedures to:

144
145 (I) comply with federal and state laws and regulations; and

146
147 (II) maintain patient confidentiality.

148
149 (iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel
150 who:

151
152 (I) are designated in writing by the pharmacist-in-charge; and
153

154 (II) have completed documented training concerning their duties associated with the
155 automated pharmacy system.

156
157 (v) Drugs shall be stored in compliance with the provisions of §291.15 of this title (relating to
158 Storage of Drugs) and §291.33(f)(2) of this title including the requirements for temperature and
159 handling of outdated drugs.

160
161 (D) Prescription dispensing and delivery.

162
163 (i) Drugs shall only be dispensed at a remote site through an automated pharmacy system
164 after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a
165 manner authorized by §291.34(b) of this title.

166
167 (ii) A pharmacist at the provider pharmacy shall control all operations of the automated
168 pharmacy system and approve the release of the initial dose of a prescription drug order.
169 Subsequent doses from an approved prescription drug order may be removed from the
170 automated medication system after this initial approval. Any change made in the prescription
171 drug order shall require a new approval by a pharmacist to release the drug.

172
173 (iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified
174 in §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy
175 system.

176
177 (iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system
178 shall comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

179
180 (v) An automated pharmacy system used to meet the emergency medication needs for
181 residents of a remote site must comply with the requirements for emergency medication kits in
182 subsection (b) of this section.

183
184 (E) Drugs.

185
186 (i) Drugs for use in an automated pharmacy system shall be packaged in the original
187 manufacturer's container or be prepackaged in the provider pharmacy and labeled in
188 compliance with the board's prepackaging requirements for the class of pharmacy.

189
190 (ii) Drugs dispensed from the automated pharmacy system may be returned to the
191 pharmacy for reuse provided the drugs are in sealed, tamper evident packaging which has not
192 been opened.

193
194 (F) Stocking an automated pharmacy system.

195
196 (i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist,
197 pharmacy technician, or pharmacy technician trainee under the direct supervision of a
198 pharmacist, except as provided in clause (ii) of this subparagraph.

199
200 (ii) If the automated pharmacy system uses removable cartridges or containers to hold
201 drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy
202 unless provided by an FDA approved repackager. The prepackaged cartridges or containers
203 may be sent to the remote site to be loaded into the machine by personnel designated by the
204 pharmacist-in-charge provided:

205
206
207
208
209
210
211
212
213
214
215
216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254
255

- (I) a pharmacist verifies the cartridge or container has been properly filled and labeled;
 - (II) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and
 - (III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.
- (iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote site by the provider pharmacy.
- (G) Quality assurance program. A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to a written program for quality assurance of the automated pharmacy system which:
- (i) requires continuous supervision of the automated pharmacy system; and
 - (ii) establishes mechanisms and procedures to routinely test the accuracy of the automated pharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.
- (H) Policies and procedures of operation.
- (i) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:
- (I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have access to the drugs stored in the automated pharmacy system;
 - (II) duties which may only be performed by a pharmacist;
 - (III) a copy of the portion of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated pharmacy system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;
 - (IV) date of last review/revision of the policy and procedure manual; and
 - (V) policies and procedures for:
 - (-a-) security;
 - (-b-) operation of the automated pharmacy system;
 - (-c-) preventative maintenance of the automated pharmacy system;
 - (-d-) sanitation;

- 256 (-e-) storage of drugs;
257
258 (-f-) dispensing;
259
260 (-g-) supervision;
261
262 (-h-) drug procurement;
263
264 (-i-) receiving of drugs;
265
266 (-j-) delivery of drugs; and
267
268 (-k-) recordkeeping.

269
270 (ii) A pharmacy that provides pharmacy services through an automated pharmacy system at
271 a remote site shall, at least annually, review its written policies and procedures, revise them if
272 necessary, and document the review.

273
274 (iii) A pharmacy providing remote pharmacy services using an automated pharmacy system
275 shall maintain a written plan for recovery from an event which interrupts the ability of the
276 automated pharmacy system to dispense prescription drugs. The written plan for recovery shall
277 include:

278
279 (I) planning and preparation for maintaining pharmacy services when an automated
280 pharmacy system is experiencing downtime;

281
282 (II) procedures for response when an automated pharmacy system is experiencing
283 downtime; and

284
285 (III) procedures for the maintenance and testing of the written plan for recovery.

286
287 (5) Records.

288
289 (A) Maintenance of records.

290
291 (i) Every record required under this section must be:

292
293 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
294 copying by the board or its representative and to other authorized local, state, or federal law
295 enforcement agencies; and

296
297 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent
298 of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
299 format, the requested records must be provided in an electronic format if specifically requested
300 by the board or its representative. Failure to provide the records set out in this section, either on
301 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
302 in violation of the Act.

303
304 (ii) The provider pharmacy shall maintain original prescription drug orders for drugs
305 dispensed from an automated pharmacy system in compliance with §291.34(b) of this title.
306

307 (iii) if prescription drug records are maintained in a data processing system, the system shall
308 have a workable (electronic) data retention system which can produce a separate audit trail of
309 drug usage by the provider pharmacy and each remote site for the preceding two years as
310 specified in §291.34(e) of this title.

311
312 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this
313 title.

314
315 (C) Records of dispensing. Dispensing records for a prescription drug order shall be
316 maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

317
318 (D) Transaction information.

319
320 (i) The automated pharmacy system shall electronically record all transactions involving
321 drugs stored in, removed, or dispensed from the system.

322
323 (ii) Records of dispensing from an automated pharmacy system for a patient shall be
324 maintained by the providing pharmacy and include the:

325
326 (I) identity of the system accessed;

327
328 (II) identification of the individual accessing the system;

329
330 (III) date of transaction;

331
332 (IV) name, strength, dosage form, and quantity of drug accessed; and

333
334 (V) name of the patient for whom the drug was accessed.

335
336 (iii) Records of stocking or removal from an automated pharmacy system shall be
337 maintained by the pharmacy and include the:

338
339 (I) date;

340
341 (II) name, strength, dosage form, and quantity of drug stocked or removed;

342
343 (III) name, initials, or identification code of the person stocking or removing drugs from the
344 system;

345
346 (IV) name, initials, or identification code of the pharmacist who checks and verifies that the
347 system has been accurately filled;

348
349 (E) Patient medication records. Patient medication records shall be created and maintained
350 by the provider pharmacy in the manner required by §291.34(c) of this title.

351
352 (F) Inventory.

353
354 (i) A provider pharmacy shall:

355
356 (I) keep a record of all drugs sent to and returned from a remote site separate from the
357 records of the provider pharmacy and from any other remote site's records; and

358
359
360
361
362
363
364
365
366
367
368
369
370
371
372
373
374
375
376
377
378
379
380
381
382
383
384
385
386
387
388
389
390
391
392
393
394
395
396
397
398
399
400
401
402
403
404
405
406
407
408

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title (relating to Inventory Requirements for All Classes of Pharmacies) that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(b) Remote pharmacy services using emergency medication kits.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an emergency medication kit as outlined in §562.108 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this subsection, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Emergency medication kits--Controlled substances and dangerous drugs maintained by a provider pharmacy to meet the emergency medication needs of a resident:

(i) at an institution licensed under Chapter 242 or 252, Health and Safety Code; or

(ii) at an institution licensed under Chapter 242, Health and Safety Code and that is a veterans home as defined by the §164.002, Natural Resources Code, if the provider pharmacy is a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy.

(C) Remote site--A facility not located at the same location as a Class A, Class C, Class E pharmacy or a United States Department of Affairs pharmacy or another federally operated pharmacy, at which remote pharmacy services are provided using an emergency medication kit.

(D) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an emergency medication kit.

(E) Provider pharmacy--The community pharmacy (Class A), the institutional pharmacy (Class C), the non-resident (Class E) pharmacy located not more than 20 miles from an institution licensed under Chapter 242 or 252, Health and Safety Code, or the United States Department of Veterans Affairs pharmacy or another federally operated pharmacy providing remote pharmacy services.

409
410 (F) Remote pharmacy service--The provision of pharmacy services, including the storage and
411 dispensing of prescription drugs, in remote sites.

412
413 (3) General requirements.

414
415 (A) A provider pharmacy may provide remote pharmacy services using an emergency
416 medication kit to an institution regulated under Chapter 242, or 252, Health and Safety Code.

417
418 (B) A provider pharmacy may provide remote pharmacy services at more than one remote
419 site.

420
421 (C) A provider pharmacy shall not place an emergency medication kit in a remote site which
422 already has a kit from another provider pharmacy except as provided by paragraph (4)(B)(iii) of
423 this subsection.

424
425 (D) A provider pharmacy which is licensed as an institutional (Class C) or a non-resident
426 (Class E) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title
427 and this section.

428
429 (E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy
430 operations involving the emergency medication kit located at the remote site including
431 supervision of the emergency medication kit and compliance with this section.

432
433 (4) Operational standards.

434
435 (A) Application for permission to provide pharmacy services using an emergency medication
436 kit.

437
438 (i) A Class A, Class C, or Class E Pharmacy shall make application to the board to provide
439 remote pharmacy services using an emergency medication kit. The application shall contain an
440 affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or
441 the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief
442 executive officer, chief operating officer), and include the following:

443
444 (I) the name, address, and license number of the provider pharmacy;

445
446 (II) name and address of the healthcare facility where the remote pharmacy services will be
447 provided;

448
449 (III) a statement indicating that the provider pharmacy and the healthcare facility have
450 entered into a written contract or agreement which outlines the services to be provided and the
451 responsibilities and accountabilities of each party in fulfilling the terms of the contract or
452 agreement in compliance with federal and state laws and regulations;

453
454 (IV) documentation that the emergency medication kit is located in a facility regulated
455 under Chapter 242, or 252, Health and Safety Code; and

456
457 (V) if applicable, documentation that the emergency kit is located in a facility that is not
458 more than 20 miles from the Class E pharmacy providing the emergency kit.

459

460 (ii) Such application shall be resubmitted every two years in conjunction with the application
461 for renewal of the provider pharmacy's license. The renewal petition shall contain the
462 documentation required in clause (i) of this subparagraph except the notarized signature of the
463 medical director or the person responsible for the on-site operation of the facility (e.g.,
464 administrator, owner, chief executive officer, chief operating officer) is not required.
465

466 (iii) Upon approval of the application, the provider pharmacy will be sent a certificate which
467 must be displayed at the remote site.
468

469 (B) Notification requirements.
470

471 (i) A provider pharmacy shall notify the board in writing within ten days of a change of
472 location, discontinuance of service, or closure of:

473 (I) a remote site where an emergency medication kit is operated by the pharmacy; or
474

475 (II) a remote pharmacy service at a remote site.
476

477 (ii) A provider pharmacy shall comply with appropriate federal and state controlled
478 substance registrations for each remote site if controlled substances are maintained within an
479 emergency medication kit at the facility.
480

481 (iii) If more than one provider pharmacy provides an emergency kit to a remote site, the
482 provider pharmacies must enter into a written agreement as to the emergency medications
483 supplied by each pharmacy. The provider pharmacies shall not duplicate drugs stored in the
484 emergency medication kits. The written agreement shall include reasons why an additional
485 pharmacy is required to meet the emergency medication needs of the residents of the
486 institution.
487

488 (C) Environment/Security.
489

490 (i) Emergency medication kits shall have adequate security and procedures to:

491 (I) prohibit unauthorized access;
492

493 (II) comply with federal and state laws and regulations; and
494

495 (III) maintain patient confidentiality.
496

497 (ii) Access to the emergency medication kit shall be limited to pharmacists and licensed
498 healthcare personnel employed by the facility.
499

500 (iii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of
501 this title including the requirements for temperature and handling outdated drugs.
502

503 (D) Prescription dispensing and delivery.
504

505 (i) Drugs in the emergency medication kit shall be accessed for administration to meet the
506 emergency medication needs of a resident of the remote site pursuant to an order from a
507 practitioner. The prescription drug order for the drugs used from the emergency medication kit
508 shall be forwarded to the provider pharmacy in a manner authorized by §291.34(b) of this title.
509
510

511
512 (ii) The remote site shall notify the provider pharmacy of each entry into an emergency
513 medication kit. Such notification shall meet the requirements of paragraph (5)(D)(ii) of this
514 subsection.

515
516 (E) Drugs.

517
518 (i) The contents of an emergency medication kit:

519
520 (I) may consist of dangerous drugs and controlled substances; and

521
522 (II) shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider
523 pharmacy, medical director, and the director of nurses and limited to those drugs necessary to
524 meet the resident's emergency medication needs. For the purpose of this subsection, this shall
525 mean a situation in which a drug cannot be supplied by a pharmacy within a reasonable time
526 period.

527
528 (ii) When deciding on the drugs to be placed in the emergency medication kit, the consultant
529 pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of
530 nurses must determine, select, and record a prudent number of drugs for potential emergency
531 incidents based on:

532
533 (I) clinical criteria applicable to each facility's demographics;

534
535 (II) the facility's census; and

536
537 (III) the facility's healthcare environment.

538
539 (iii) A current list of the drugs stored in each remote site's emergency medication kit shall be
540 maintained by the provider pharmacy and a copy kept with the emergency medication kit.

541
542 (iv) An automated pharmacy system may be used as an emergency medication kit provided
543 the system limits emergency access to only those drugs approved for the emergency
544 medication kit.

545
546 (v) Drugs for use in an emergency medication kit shall be packaged in the original
547 manufacturer's container or prepackaged in the provider pharmacy and labeled in compliance
548 with the board's prepackaging requirements for the class of pharmacy.

549
550 (F) Stocking emergency medication kits.

551
552 (i) Stocking of drugs in an emergency medication kit shall be completed at the provider
553 pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee
554 under the direct supervision of a pharmacist, except as provided in clause (ii) of this
555 subparagraph.

556
557 (ii) If the emergency medication kit is an automated pharmacy system which uses
558 removable cartridges or containers to hold drugs, the prepackaging of the cartridges or
559 containers shall occur at the provider pharmacy unless provided by and FDA approved
560 repackager. The prepackaged cartridges or containers may be sent to the remote site to be
561 loaded into the machine by personnel designated by the pharmacist-in-charge provided:

562
563 (I) a pharmacist verifies the cartridge or container has been properly filled and labeled;
564
565 (II) the individual cartridges or containers are transported to the remote site in a secure,
566 tamper-evident container; and
567
568 (III) the automated pharmacy system uses bar-coding, microchip, or other technologies to
569 ensure that the containers are accurately loaded in the automated pharmacy system.
570
571 (iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote
572 site by the provider pharmacy.
573
574 (G) Policies and procedures of operation.
575
576 (i) A provider pharmacy that provides pharmacy services through an emergency medication
577 kit at a remote site shall operate according to written policies and procedures. The policy and
578 procedure manual shall include, but not be limited to, the following:
579
580 (I) duties which may only be performed by a pharmacist;
581
582 (II) a copy of the written contract or agreement between the pharmacy and the facility
583 which outlines the services to be provided and the responsibilities and accountabilities of each
584 party in fulfilling the terms of the contract in compliance with federal and state laws and
585 regulations;
586
587 (III) date of last review/revision of the policy and procedure manual; and
588
589 (IV) policies and procedures for:
590
591 (-a-) security;
592
593 (-b-) operation of the emergency medication kit;
594
595 (-c-) preventative maintenance of the automated pharmacy system if the emergency
596 medication kit is an automated pharmacy system;
597
598 (-d-) sanitation;
599
600 (-e-) storage of drugs;
601
602 (-f-) dispensing;
603
604 (-g-) supervision;
605
606 (-h-) drug procurement;
607
608 (-i-) receiving of drugs;
609
610 (-j-) delivery of drugs; and
611
612 (-k-) recordkeeping.

613
614 (ii) A pharmacy that provides pharmacy services through an emergency medication kit at a
615 remote site shall, at least annually, review its written policies and procedures, revise them if
616 necessary, and document the review.

617
618 (iii) A pharmacy providing remote pharmacy services using an emergency medication kit
619 which is an automated pharmacy system shall maintain a written plan for recovery from an
620 event which interrupts the ability of the automated pharmacy system to provide emergency
621 medications. The written plan for recovery shall include:

622
623 (I) planning and preparation for maintaining pharmacy services when an automated
624 pharmacy system is experiencing downtime;

625
626 (II) procedures for response when an automated pharmacy system is experiencing
627 downtime; and

628
629 (III) procedures for the maintenance and testing of the written plan for recovery.

630
631 (5) Records.

632
633 (A) Maintenance of records.

634
635 (i) Every record required under this section must be:

636
637 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
638 copying by the board or its representative and to other authorized local, state, or federal law
639 enforcement agencies; and

640
641 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent
642 of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
643 format, the requested records must be provided in an electronic format if specifically requested
644 by the board or its representative. Failure to provide the records set out in this section, either on
645 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
646 in violation of the Act.

647
648 (ii) The provider pharmacy shall maintain original prescription drug orders for drugs
649 dispensed from an emergency medication kit in compliance with §291.34(b) of this title.

650
651 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this
652 title.

653
654 (C) Records of dispensing. Dispensing records for a prescription drug order shall be
655 maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

656
657 (D) Transaction information.

658
659 (i) A prescription drug order shall be maintained by the provider pharmacy as the record of
660 removal of a drug from an emergency medication kit for administration to a patient.

661
662 (ii) The remote site shall notify the provider pharmacy electronically or in writing of each
663 entry into an emergency medication kit. Such notification may be included on the prescription

664 drug order or a separate document and shall include the name, strength, and quantity of the
665 drug removed, the time of removal, and the name of the person removing the drug.

666
667 (iii) A separate record of stocking, removal, or dispensing for administration from an
668 emergency medication kit shall be maintained by the pharmacy and include the:

669 (I) date;

670
671 (II) name, strength, dosage form, and quantity of drug stocked, removed, or dispensed for
672 administration;

673
674 (III) name, initials, or identification code of the person stocking, removing, or dispensing for
675 administration, drugs from the system;

676
677 (IV) name, initials, or identification code of the pharmacist who checks and verifies that the
678 system has been accurately filled; and

679
680 (V) unique prescription number assigned to the prescription drug order when the drug is
681 administered to the patient.

682
683 (E) Inventory.

684 (i) A provider pharmacy shall:

685 (I) keep a record of all drugs sent to and returned from a remote site separate from the
686 records of the provider pharmacy and from any other remote site's records; and

687
688 (II) keep a perpetual inventory of controlled substances and other drugs required to be
689 inventoried under §291.17 of this title, that are received and dispensed or distributed from each
690 remote site.

691 (ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at
692 each remote site. The following is applicable to this inventory.

693 (I) The inventory of each remote site and the provider pharmacy shall be taken on the
694 same day.

695 (II) The inventory of each remote site shall be included with, but listed separately from, the
696 drugs of other remote sites and separately from the drugs of the provider pharmacy.

697
698 (c) Remote pharmacy services using telepharmacy systems.

699
700 (1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy
701 services by a Class A or Class C pharmacy in a healthcare facility that is not at the same
702 location as a Class A or Class C pharmacy through a telepharmacy system as outlined in
703 §562.110 of the Texas Pharmacy Act.

704
705 (2) Definitions. The following words and terms, when used in this section, shall have the
706 following meanings, unless the context clearly indicates otherwise. All other words and terms
707 shall have the meanings defined in the Act or §291.31 of this title.

713
714

715 (A) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
716 manufacturer's original commercial container into a prescription container for dispensing by a
717 pharmacist to the ultimate consumer.

718
719 (B) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy
720 (Class C) providing remote pharmacy services.

721
722 (C) Remote site--a facility not located at the same location as a Class A or Class C
723 pharmacy, at which remote pharmacy services are provided using a telepharmacy dispensing
724 system.

725
726 (D) Remote pharmacy service--The provision of pharmacy services, including the storage and
727 dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote site.

728
729 (E) Still image capture--A specific image captured electronically from a video or other image
730 capture device.

731
732 (F) Store and forward--A video or still image record which is saved electronically for future
733 review.

734
735 (G) Telepharmacy system--A system that monitors the dispensing of prescription drugs and
736 provides for related drug use review and patient counseling services by an electronic method
737 which shall include the use of the following types of technology:

738
739 (i) audio and video;

740
741 (ii) still image capture; and

742
743 (iii) store and forward.

744
745 (H) Unit-of-use--A sufficient quantity of a drug for one normal course of therapy as
746 determined by the pharmacist-in-charge and the prescribing practitioner(s) at the healthcare
747 facility.

748
749 (3) General requirements.

750
751 (A) A provider pharmacy may provide remote pharmacy services using a telepharmacy
752 system to:

753
754 (i) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;

755
756 (ii) a health center as defined by 42 U.S.C. Section 254b, as amended; or

757
758 (iii) healthcare facility located in a medically underserved area as defined by state or federal
759 law.

760
761 (B) A provider pharmacy may not provide remote pharmacy services if a Class A
762 (Community) or Class C (Institutional) pharmacy that dispenses prescription drug orders to out-
763 patients is located in the same community. For the purposes of this subsection a community is
764 defined as:

765

766 (i) the census tract in which the remote site is located, if the remote site is located in a
767 Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most
768 recent U.S. Census; or

769
770 (ii) within 10 miles of the remote site, if the remote site is not located in a MSA.
771

772 (C) The provider pharmacy shall have sufficient pharmacists on duty such that each
773 pharmacist may supervise no more than three remote sites that are simultaneously open to
774 provide services. An exception to the supervision limit may be granted by the board in situations
775 where the provider has documented a need for a pharmacist to supervise additional remote
776 sites and has demonstrated that appropriate safeguards are in place to assure proper
777 supervision of each remote site.

778
779 (D) Before providing remote pharmacy service, the telepharmacy system at the off-site facility
780 must be tested by the provider pharmacy and found to operate properly. The provider pharmacy
781 shall make the results of such testing available to the board upon request.
782

783 (E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required
784 to comply with the provisions of §§291.31 - 291.34 of this title and this section.
785

786 (F) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the
787 remote site including supervision of the telepharmacy system and compliance with this section.
788

789 (4) Operational standards.

790
791 (A) Application to provide pharmacy services using a telepharmacy system.
792

793 (i) A Class A or class C Pharmacy shall make application to the board to provide remote
794 pharmacy services using a telepharmacy system. The application shall contain an affidavit with
795 the notarized signatures of pharmacist-in-charge, and the medical director or the person
796 responsible for the on-site operation of the facility (e.g., administrator, owner, chief executive
797 officer, chief operating officer), and include the following:
798

799 (I) the name, address, and license number of the provider pharmacy;
800

801 (II) name and address of the healthcare facility where the remote pharmacy services will be
802 provided;
803

804 (III) a statement indicating that the provider pharmacy and the healthcare facility have
805 entered into a written contract or agreement which outlines the services to be provided and the
806 responsibilities and accountabilities of each party in fulfilling the terms of the contract or
807 agreement in compliance with federal and state laws and regulations;
808

809 (IV) documentation that the healthcare facility is:
810

811 (-a-) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended;
812

813 (-b-) a health center as defined by 42 U.S.C. Section 254b, as amended; or
814

815 (-c-) located in a medically underserved area as defined by state or federal law; and
816

817 (V) documentation that a Class A (Community) or Class C (Institutional) Pharmacy that
818 dispenses prescriptions drug orders to out-patients is not located within the community, as
819 defined in paragraph (3)(B) of this subsection, where the remote site is located.

820
821 (ii) Such application shall be resubmitted every two years in conjunction with the renewal of
822 the provider pharmacy's license. The renewal application shall contain the documentation
823 required in clause (i) of this subparagraph except the notarized signature of the medical director
824 or the person responsible for the on-site operation of the facility (e.g., administrator, owner, chief
825 executive officer, chief operating officer) is not required.

826
827 (iii) On approval of the application, the provider pharmacy will be sent a registration
828 certificate, which must be displayed at the remote site.

829
830 (B) Notification requirements.

831
832 (i) A provider pharmacy shall notify the board in writing within ten days of a change of
833 location, discontinuance of service, or closure of:

834
835 (I) a remote site where a telepharmacy system is operated by the pharmacy; or

836
837 (II) a remote pharmacy service at a remote site.

838
839 (ii) A provider pharmacy shall comply with appropriate federal and state controlled
840 substance registrations for each remote site, if controlled substances are maintained.

841
842 (C) Environment/Security.

843
844 (i) A remote site shall be under the continuous supervision of a provider pharmacy
845 pharmacist at all times the site is open to provide pharmacy services. To qualify as continuous
846 supervision, the pharmacist is not required to be physically present at the remote site and shall
847 supervise electronically through the use of the following types of technology:

848
849 (I) audio and video;

850
851 (II) still image capture; and

852
853 (III) store and forward.

854
855 (ii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of
856 this title including the requirements for temperature and handling of outdated drugs.

857
858 (iii) Drugs for use in the telepharmacy system shall be stored in an area that is:

859
860 (I) separate from any other drugs used by the healthcare facility; and

861
862 (II) locked by key, combination or other mechanical or electronic means, so as to prohibit
863 access by unauthorized personnel.

864
865 (iv) Access to the area where drugs are stored at the remote site and operation of the
866 telepharmacy system shall be limited to pharmacists employed by the provider pharmacy or
867 personnel who:

868
869 (I) are licensed healthcare providers pharmacy technicians or pharmacy technician
870 trainees;
871
872 (II) are designated in writing by the pharmacist-in-charge; and
873
874 (III) have completed documented training concerning their duties associated with the
875 telepharmacy pharmacy system.
876
877 (v) Remote sites shall have adequate security and procedures to:
878
879 (I) comply with federal and state laws and regulations; and
880
881 (II) maintain patient confidentiality.
882
883 (vi) The provider pharmacy shall have procedures that specify that drugs may only be
884 delivered to the remote site by the provider pharmacy and shall:
885
886 (I) be shipped in a sealed container with a list of drugs delivered;
887
888 (II) signed for on receipt by an employee of the healthcare facility;
889
890 (III) be quarantined in a locked area, if personnel designated to receive the drugs by the
891 pharmacist-in-charge is not available; and
892
893 (IV) be checked by personnel designated by the pharmacist-in-charge to verify that drugs
894 sent by the provider pharmacy were actually received. The designated person who checks the
895 order shall document the verification by signing and dating the list of drugs delivered.
896
897 (D) Prescription dispensing and delivery.
898
899 (i) Drugs shall only be dispensed at the remote site through a telepharmacy system after
900 receipt of an original prescription drug order by a pharmacist at the provider pharmacy in the
901 manner authorized by §291.34(b) of this title.
902
903 (ii) Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a
904 remote site only in unit-of-use containers that are:
905
906 (I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled
907 as specified in §291.33(c)(6) of this title; or
908
909 (II) in original manufacturer's containers.
910
911 (iii) The following duties shall be performed only by a pharmacist at the provider pharmacy:
912
913 (I) receiving an oral prescription drug order;
914
915 (II) interpret the prescription drug order;
916
917 (III) verify the accuracy of prescription data entry;
918

919 (IV) select the drug product;
920
921 (V) interpret the patient's medication record and conduct a drug regimen review as
922 specified in clause (iv) of this subparagraph;
923
924 (VI) authorize the telepharmacy system to print a prescription label at the remote site as
925 specified in clause (v) of this subparagraph;
926
927 (VII) perform the final check of the dispensed prescription as specified in clause (vi) of this
928 subparagraph to ensure that the prescription drug order has been dispensed accurately as
929 prescribed;
930
931 (VIII) counsel the patient as specified clause (vii) of this subparagraph.
932
933 (iv) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified
934 in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's
935 agent.
936
937 (v) The dispensed prescription shall be labeled at the remote site with the information
938 specified in §291.33(c) of this title except that:
939
940 (I) the label shall contain both the name, address, and phone number of the provider
941 pharmacy and the name and address of the remote site; and
942
943 (II) the unique identification number of the prescription on the label shall in some manner
944 identify the remote site which dispensed the prescription using a telepharmacy system.
945
946 (vi) A pharmacist at the provider pharmacy shall perform the final check of the dispensed
947 prescription before delivery to the patient to ensure that the prescription has been dispensed
948 accurately as prescribed. This final check shall be accomplished through a visual check using
949 electronic methods.
950
951 (vii) A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as
952 specified in §291.33(c) of this title. This counseling may be performed using electronic methods.
953 Non-pharmacist personnel may not ask questions of a patient or patient's agent which are
954 intended to screen and/or limit interaction with the pharmacist.
955
956 (viii) If the remote site has direct access to the provider pharmacy's data processing system,
957 only a pharmacist, pharmacy technician, or pharmacy technician trainee may enter prescription
958 information into the data processing system. The original prescription shall be sent to the
959 provider pharmacy and a pharmacist shall verify the accuracy of the data entry.
960
961 (ix) Drugs which require reconstitution through the addition of a specified amount of water
962 may be dispensed by the remote site only if a pharmacy technician, pharmacy technician
963 trainee, or licensed healthcare provider reconstitutes the product.
964
965 (E) Quality assurance program. A pharmacy that provides pharmacy services through a
966 telepharmacy system at a remote site shall operate according to a written program for quality
967 assurance of the telepharmacy system which:
968

969 (i) requires continuous supervision of the telepharmacy system at all times the site is open
970 to provide pharmacy services; and

971
972 (ii) establishes mechanisms and procedures to routinely test the operation of the
973 telepharmacy system at a minimum of every six months and whenever any upgrade or change
974 is made to the system and documents each such activity.

975
976 (F) Policies and procedures.

977
978 (i) A pharmacy that provides pharmacy services through a telepharmacy system at a remote
979 site shall operate according to written policies and procedures. The policy and procedure
980 manual shall include, but not be limited to, the following:

981
982 (I) a current list of the name and address of the pharmacist-in-charge and personnel
983 designated by the pharmacist-in-charge to have:

984
985 (-a-) have access to the area where drugs are stored at the remote site; and

986
987 (-b-) operate the telepharmacy system;

988
989 (II) duties which may only be performed by a pharmacist;

990
991 (III) a copy of the written contract or agreement between the provider pharmacy and the
992 healthcare facility which outlines the services to be provided and the responsibilities and
993 accountabilities of each party in fulfilling the terms of the contract or agreement in compliance
994 with federal and state laws and regulations;

995
996 (IV) date of last review/revision of policy and procedure manual; and

997
998 (V) policies and procedures for:

999
1000 (-a-) security;

1001
1002 (-b-) operation of the telepharmacy system;

1003
1004 (-c-) sanitation;

1005
1006 (-d-) storage of drugs;

1007
1008 (-e-) dispensing;

1009
1010 (-f-) supervision;

1011
1012 (-g-) drug and/or device procurement;

1013
1014 (-h-) receiving of drugs and/or devices;

1015
1016 (-i-) delivery of drugs and/or devices; and

1017
1018 (-j-) recordkeeping

1019

1020 (ii) A pharmacy that provides pharmacy services through a telepharmacy system at a
1021 remote site shall, at least annually, review its written policies and procedures, revise them if
1022 necessary, and document the review.

1023
1024 (iii) A pharmacy providing remote pharmacy services through a telepharmacy system shall
1025 maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to
1026 electronically supervise the telepharmacy system and the dispensing of prescription drugs at the
1027 remote site. The written plan for recovery shall include:

1028
1029 (I) a statement that prescription drugs shall not be dispensed at the remote site, if a
1030 pharmacist is not able to electronically supervise the telepharmacy system and the dispensing
1031 of prescription drugs;

1032
1033 (II) procedures for response when a telepharmacy system is experiencing downtime; and

1034
1035 (III) procedures for the maintenance and testing of the written plan for recovery.

1036
1037 (5) Records.

1038
1039 (A) Maintenance of records.

1040
1041 (i) Every record required under this section must be:

1042
1043 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
1044 copying by the board or its representative and to other authorized local, state, or federal law
1045 enforcement agencies; and

1046
1047 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent
1048 of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
1049 format, the requested records must be provided in an electronic format if specifically requested
1050 by the board or its representative. Failure to provide the records set out in this section, either on
1051 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
1052 in violation of the Act.

1053
1054 (ii) The provider pharmacy shall maintain original prescription drug orders for medications
1055 dispensed from a remote site using a telepharmacy system in the manner required by
1056 §291.34(b) of this title.

1057
1058 (iii) If prescription drug records are maintained in a data processing system, the system shall
1059 have a workable (electronic) data retention system which can produce a separate audit trail of
1060 drug usage by the provider pharmacy and by each remote site for the preceding two years as
1061 specified in §291.34(e) of this title.

1062
1063 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this
1064 title.

1065
1066 (C) Patient medication records. Patient medication records shall be created and maintained
1067 at the provider pharmacy in the manner required by §291.34(c) of this title.

1068
1069 (D) Inventory.

1070

1071
1072
1073
1074
1075
1076
1077
1078
1079
1080
1081
1082
1083
1084
1085
1086
1087
1088
1089
1090
1091
1092
1093
1094
1095
1096
1097
1098
1099
1100
1101
1102
1103
1104
1105
1106
1107
1108
1109
1110
1111
1112
1113
1114
1115
1116
1117
1118
1119
1120
1121

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records;

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title, that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title. A provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs at the provider pharmacy.

§291.123 Central Prescription Drug or Medication Order Processing

(a) Purpose.

(1) The purpose of this section is to provide standards for centralized prescription drug or medication order processing by a Class A (Community), Class C (Institutional), or Class E (Non-Resident) pharmacy.

(2) Any facility established for the purpose of processing prescription drug or medication drug orders shall be licensed as a Class A, Class C, or Class E pharmacy under the Act. However, nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in Texas from remotely accessing the pharmacy's electronic data base from outside the pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act. Centralized prescription drug or medication order processing--the processing of a prescription drug or medication orders by a Class A, Class C, or Class E pharmacy on behalf of another pharmacy, a health care provider, or a payor. Centralized prescription drug or medication order processing does not include the dispensing of a prescription drug order but includes any of the following:

- (1) receiving, interpreting, or clarifying prescription drug or medication drug orders;
- (2) data entering and transferring of prescription drug or medication order information;
- (3) performing drug regimen review;
- (4) obtaining refill and substitution authorizations;
- (5) interpreting clinical data for prior authorization for dispensing;

1122
1123 (6) performing therapeutic interventions; and
1124
1125 (7) providing drug information concerning a patient's prescription.
1126
1127 (c) Operational Standards.
1128
1129 (1) General requirements.
1130
1131 (A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication
1132 order processing to another Class A, Class C, or Class E pharmacy provided the pharmacies:
1133
1134 (i) have:
1135
1136 (I) the same owner; or
1137
1138 (II) entered into a written contract or agreement which outlines the services to be provided
1139 and the responsibilities and accountabilities of each pharmacy in compliance with federal and
1140 state laws and regulations; and
1141
1142 (ii) share a common electronic file or have appropriate technology to allow access to
1143 sufficient information necessary or required to process a non-dispensing function.
1144
1145 (B) A pharmacy that performs centralized prescription drug or medication order processing
1146 shall comply with the provisions applicable to the class of pharmacy contained in either
1147 §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards,
1148 Records, and Official Prescription Requirements in Class A (Community) Pharmacies), or
1149 §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and
1150 Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this title (relating to
1151 Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident)
1152 Pharmacy) to the extent applicable for the specific processing activity and this section including:
1153
1154 (i) duties which must be performed by a pharmacist; and
1155
1156 (ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.
1157
1158 (2) Notifications to patients.
1159
1160 (A) A pharmacy that outsources prescription drug or medication order processing to another
1161 pharmacy shall prior to outsourcing their prescription:
1162
1163 (i) notify patients that prescription processing may be outsourced to another pharmacy; and
1164
1165 (ii) give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies
1166 under common ownership and any of the network pharmacies may process the prescription, the
1167 patient shall be notified of this fact. Such notification may be provided through a one-time written
1168 notice to the patient or through use of a sign in the pharmacy.
1169
1170 (B) The provisions of this paragraph do not apply to patients in facilities where drugs are
1171 administered to patients by a person required to do so by the laws of the state (i.e., hospitals or
1172 nursing homes).

1173
1174 (3) Policy and Procedures. A policy and procedure manual as it relates to central processing
1175 shall be maintained at all pharmacies involved in central processing and be available for
1176 inspection. Each pharmacy is required to maintain only those portions of the policy and
1177 procedure manual that relate to that pharmacy's operations. The manual shall:

1178 (A) outline the responsibilities of each of the pharmacies;

1180 (B) include a list of the name, address, telephone numbers, and all license/registration
1181 numbers of the pharmacies involved in centralized prescription drug or medication order
1182 processing; and
1183

1184 (C) include policies and procedures for:

1186 (i) protecting the confidentiality and integrity of patient information;

1188 (ii) maintenance of appropriate records to identify the name(s), initials, or identification
1189 code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any
1190 processing;
1191

1192 (iii) complying with federal and state laws and regulations;

1194 (iv) operating a continuous quality improvement program for pharmacy services designed to
1195 objectively and systematically monitor and evaluate the quality and appropriateness of patient
1196 care, pursue opportunities to improve patient care, and resolve identified problems; and
1197

1198 (v) annually reviewing the written policies and procedures and documenting such review.
1199

1200 (d) Records. All pharmacies shall maintain appropriate records which identify, by prescription
1201 drug or medication order, the name(s), initials, or identification code(s) of each pharmacist,
1202 pharmacy technician, or pharmacy technician trainee who performs a processing function for a
1203 prescription drug or medication order. Such records may be maintained:

1205 (1) separately by each pharmacy and pharmacist; or
1206

1207 (2) in a common electronic file as long as the records are maintained in such a manner that the
1208 data processing system can produce a printout which lists the functions performed by each
1209 pharmacy and pharmacist.
1210

1211

1212

1213 **§291.125 Centralized Prescription Dispensing**

1214

1215 (a) Purpose. The purpose of this section is to provide standards for centralized prescription
1216 dispensing by a Class A (Community), Class C (Institutional) pharmacy, or Class E (Non-
1217 Resident) Pharmacy.

1218

1219 (b) Definitions. The following words and terms, when used in this section, shall have the
1220 following meanings, unless the context clearly indicates otherwise. Any term not defined in this
1221 section shall have the definition set out in the Act. Centralized prescription dispensing--the
1222 dispensing or refilling of a prescription drug order by a Class A (Community), Class C
1223 (Institutional), or Class E (Non-Resident) pharmacy at the request of another Class A

1224 (Community), or Class C (Institutional) and the return of the dispensed prescriptions to the
1225 requesting pharmacy for delivery to the patient or patient's agent, or at the request of the
1226 requesting pharmacy, direct delivery to the patient.

1227

1228 (c) Operational standards.

1229

1230 (1) General requirements.

1231

1232 (A) A Class A (Community) or Class C (Institutional) pharmacy may outsource prescription
1233 drug order dispensing to another Class A (Community), Class C (Institutional), or Class E (Non-
1234 Resident) pharmacy provided the pharmacies:

1235

1236 (i) have:

1237

1238 (I) the same owner; or

1239

1240 (II) entered into a written contract or agreement which outlines the services to be provided
1241 and the responsibilities and accountabilities of each pharmacy in compliance with federal and
1242 state laws and regulations; and

1243

1244 (ii) share a common electronic file or have appropriate technology to allow access to
1245 sufficient information necessary or required to dispense or process a prescription drug order.

1246

1247 (B) The pharmacist-in-charge of the dispensing pharmacy shall ensure that:

1248

1249 (i) the pharmacy maintains and uses adequate storage or shipment containers and shipping
1250 processes to ensure drug stability and potency. Such shipping processes shall include the use
1251 of appropriate packaging material and/or devices to ensure that the drug is maintained at an
1252 appropriate temperature range to maintain the integrity of the medication throughout the delivery
1253 process; and

1254

1255 (ii) the dispensed prescriptions are shipped in containers which are sealed in a manner as to
1256 show evidence of opening or tampering.

1257

1258 (C) A Class A (Community) or Class C (Institutional) dispensing pharmacy shall comply with
1259 the provisions of §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational
1260 Standards, Records, and Official Prescription Requirements in Class A (Community)
1261 Pharmacies) and this section.

1262

1263 (D) A Class E (Non-Resident) dispensing pharmacy shall comply with §§291.101 - 291.105 of
1264 this title (relating to Purpose, Definitions, Personnel, Operational Standards, and Records in
1265 Class E (Non-Resident) Pharmacies) and this section.

1266

1267 (E) Pharmacies dispensing compounded non-sterile or sterile preparations shall comply with
1268 the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
1269 Preparations) and §291.133 of this title (relating to Pharmacies Compounding Sterile
1270 Preparations).

1271

1272 (2) Notifications to patients.

1273

1274 (A) A pharmacy that outsources prescription dispensing to another pharmacy shall:

1275
1276 (i) prior to outsourcing the prescription:
1277
1278 (I) notify patients that their prescription may be outsourced to another pharmacy; and
1279
1280 (II) give the name of that pharmacy or if the pharmacy is part of a network of pharmacies
1281 under common ownership and any of the network pharmacies may dispense the prescription,
1282 the patient shall be notified of this fact. Such notification may be provided through a one-time
1283 written notice to the patient or through use of a sign in the pharmacy; and
1284
1285 (ii) if the prescription is delivered directly to the patient by the dispensing pharmacy and not
1286 returned to the requesting pharmacy, place on the prescription container or on a separate sheet
1287 delivered with the prescription container, in both English and Spanish, the local, and if
1288 applicable, the toll-free telephone number of the pharmacy and the statement: "Written
1289 information about this prescription has been provided for you. Please read this information
1290 before you take the medication. If you have questions concerning this prescription, a pharmacist
1291 is available during normal business hours to answer these questions at (insert the pharmacy's
1292 local and toll-free telephone numbers)."
1293
1294 (B) The provisions of this paragraph do not apply to patients in facilities where drugs are
1295 administered to patients by a person required to do so by the laws of the state (i.e., hospitals or
1296 nursing homes).
1297
1298 (3) Prescription Labeling. The dispensing pharmacy shall:
1299
1300 (A) place on the prescription label, the name and address or name and pharmacy license
1301 number of the pharmacy dispensing the prescription and the name and address of the
1302 pharmacy which receives the dispensed prescription;
1303
1304 (B) indicate in some manner which pharmacy dispensed the prescription (e.g., "Filled by ABC
1305 Pharmacy for XYZ Pharmacy"); and
1306
1307 (C) comply with all other labeling requirements in §291.33 of this title.
1308
1309 (4) Policies and Procedures. A policy and procedure manual as it relates to centralized
1310 dispensing shall be maintained at both pharmacies and be available for inspection. Each
1311 pharmacy is required to maintain only those portions of the policy and procedure manual that
1312 relate to that pharmacy's operations. The manual shall:
1313
1314 (A) outline the responsibilities of each of the pharmacies;
1315
1316 (B) include a list of the name, address, telephone numbers, and all license/registration
1317 numbers of the pharmacies involved in centralized prescription dispensing; and
1318
1319 (C) include policies and procedures for:
1320
1321 (i) notifying patients that their prescription may be outsourced to another pharmacy for
1322 centralized prescription dispensing and providing the name of that pharmacy;
1323
1324 (ii) protecting the confidentiality and integrity of patient information;
1325

- 1326 (iii) dispensing prescription drug orders when the filled order is not received or the patient
1327 comes in before the order is received;
- 1328
1329 (iv) complying with federal and state laws and regulations;
- 1330
1331 (v) operating a continuous quality improvement program for pharmacy services designed to
1332 objectively and systematically monitor and evaluate the quality and appropriateness of patient
1333 care, pursue opportunities to improve patient care, and resolve identified problems; and
1334
- 1335 (vi) annually reviewing the written policies and procedures and documenting such review.
1336
- 1337 (d) Records.
- 1338
1339 (1) Records may be maintained in an alternative data retention system, such as a data
1340 processing system or direct imaging system provided:
- 1341
1342 (A) the records maintained in the alternative system contain all of the information required on
1343 the manual record; and
1344
- 1345 (B) the data processing system is capable of producing a hard copy of the record upon the
1346 request of the board, its representative, or other authorized local, state, or federal law
1347 enforcement or regulatory agencies.
1348
- 1349 (2) Each pharmacy shall comply with all the laws and rules relating to the maintenance of
1350 records and be able to produce an audit trail showing all prescriptions dispensed by the
1351 pharmacy.
1352
- 1353 (3) The requesting pharmacy shall maintain records which indicate the date:
- 1354
1355 (A) the request for dispensing was transmitted to the dispensing pharmacy; and
1356
- 1357 (B) the dispensed prescription was received by the requesting pharmacy, including the
1358 method of delivery (e.g., private, common, or contract carrier) and the name of the person
1359 accepting delivery.
1360
- 1361 (4) The dispensing pharmacy shall maintain records which indicate:
- 1362
1363 (A) the date the prescription was shipped to the requesting pharmacy;
- 1364
1365 (B) the name and address where the prescription was shipped; and
1366
- 1367 (C) the method of delivery (e.g., private, common, or contract carrier).
1368
1369

1370 **§291.127 Emergency Remote Pharmacy License**

- 1371
1372 (a) Definitions. The following words and terms, when used in this section, shall have the
1373 following meanings, unless the context clearly indicates otherwise. All other words and terms
1374 shall have the meanings defined in the Act.
1375

1376 (1) Emergency remote pharmacy--A pharmacy not located at the same Texas location as a
1377 home pharmacy at which pharmacy services are provided during an emergency situation.

1378
1379 (2) Emergency situation--An emergency caused by a natural or manmade disaster or any other
1380 exceptional situation that causes an extraordinary demand for pharmacy services.

1381
1382 (3) Home pharmacy--A currently licensed Class A (Community), Class C (Institutional), or
1383 Class D (Clinic) pharmacy that is providing emergency pharmacy services through an
1384 emergency remote pharmacy.

1385
1386 (b) Emergency remote pharmacy license. In an emergency situation, the board may grant a
1387 holder of a Class A (Community), Class C (Institutional), or Class D (Clinic) pharmacy license,
1388 the authority to operate a pharmacy and provide pharmacy services at an alternate location.
1389 The following is applicable for the emergency remote pharmacy.

1390
1391 (1) The emergency remote pharmacy will not be issued a separate pharmacy license, but shall
1392 operate under the license of the home pharmacy. To qualify for an emergency remote pharmacy
1393 license, the applicant must submit an application including the following information:

1394
1395 (A) license number, name, address, and phone number of the home pharmacy;

1396
1397 (B) name, address, and phone number of the emergency remote pharmacy;

1398
1399 (C) name and Texas pharmacist license number of the pharmacist-in-charge of the home
1400 pharmacy and of the pharmacist-in-charge of the emergency remote pharmacy; and

1401
1402 (D) any other information required by the board.

1403
1404 (2) The board will notify the home pharmacy of the approval of an emergency remote
1405 pharmacy license.

1406
1407 (3) The emergency remote pharmacy license shall be valid for a period as determined by the
1408 board not to exceed six months. The executive director of the board, in his/her discretion, may
1409 renew the remote license for an additional six months, if the emergency situation still exists and
1410 the holder of the license shows good cause for emergency remote pharmacy to continue
1411 operation.

1412
1413 (4) The emergency remote pharmacy shall have a written contract or agreement with the home
1414 pharmacy which outlines the services to be provided and the responsibilities and
1415 accountabilities of the remote and home pharmacy in fulfilling the terms of the contract or
1416 agreement in compliance with federal and state laws and regulations.

1417
1418 (5) The home pharmacy shall designate a pharmacist to serve as the pharmacist-in-charge of
1419 the emergency remote pharmacy.

1420
1421 (6) The emergency remote pharmacy shall comply with the rules for the class of pharmacy
1422 under which the home pharmacy is licensed. A Class A pharmacy shall comply with the rules
1423 under Subchapter B of this chapter titled Community Pharmacy (Class A). A Class C pharmacy
1424 shall comply with the rules under Subchapter D of this chapter titled Institutional Pharmacy
1425 (Class C). A Class D pharmacy shall comply with the rules under Subchapter E of this chapter
1426 titled Clinic Pharmacy (Class D).

1427
1428
1429
1430
1431
1432
1433
1434
1435
1436
1437
1438
1439
1440
1441
1442
1443
1444
1445
1446
1447
1448
1449
1450
1451
1452
1453
1454
1455
1456
1457
1458
1459
1460
1461
1462
1463
1464
1465
1466
1467
1468
1469
1470
1471
1472
1473
1474
1475
1476

(7) The records of services provided at the emergency remote pharmacy shall be:

(A) kept by the home pharmacy and be available, for at least two years from the date of provision of the service, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

§291.129 Satellite Pharmacy

(a) Purpose. The purpose of this section is to create a new class of pharmacy for the provision of pharmacy services by a Class A or Class C pharmacy in a location that is not at the same location as a Class A or Class C pharmacy through a satellite pharmacy and to provide standards for the operation of this class of pharmacy established under §560.053 of the Texas Pharmacy Act.

(b) Definitions. The following words and terms, when used in the section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(1) Provider pharmacy--The Class A or Class C pharmacy providing satellite pharmacy services.

(2) Satellite pharmacy--A facility not located at the same location as a Class A or Class C pharmacy at which satellite pharmacy services are provided.

(3) Satellite pharmacy services--The provision of pharmacy services, including the storage and delivery of prescription drugs, in an alternate location.

(c) General requirements.

(1) A Class A or Class C provider pharmacy may establish a satellite pharmacy in a location that is not at the same location as a Class A or Class C pharmacy.

(2) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the satellite pharmacy including supervision of satellite pharmacy personnel and compliance with this section.

(3) A satellite pharmacy may not store bulk drugs and may only store prescription medications that have been previously verified and dispensed by the provider pharmacy.

(4) A Class C pharmacy that is a provider pharmacy dispensing outpatient prescriptions for a satellite pharmacy shall comply with the provisions of §§291.31 - 291.34 of this title (relating to

1477 Definitions, Personnel, Operational Standards, and Records for Class A (Community)
1478 pharmacies) and this section.
1479
1480 (5) The provider pharmacy and the satellite pharmacy must have:
1481
1482 (A) the same owner; and
1483
1484 (B) share a common electronic file or have appropriate technology to allow access to
1485 sufficient information necessary or required to process a non-dispensing function.
1486
1487 (d) Personnel.
1488
1489 (1) All individuals working at the satellite pharmacy shall be employees of the provider
1490 pharmacy and must report their employment to the board as such.
1491
1492 (2) A satellite pharmacy shall have sufficient pharmacists on duty to operate the satellite
1493 pharmacy competently, safely, and adequately to meet the needs of the patients of the
1494 pharmacy.
1495
1496 (3) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and
1497 pharmacy technician trainees and for designating and delegating duties, other than those listed
1498 in paragraph (7) of this subsection, to pharmacy technicians and pharmacy technician trainees.
1499 Each pharmacist:
1500
1501 (A) shall verify the accuracy of all acts, tasks, and functions performed by pharmacy
1502 technicians and pharmacy technician trainees; and
1503
1504 (B) shall be responsible for any delegated act performed by pharmacy technicians and
1505 pharmacy technician trainees under his or her supervision.
1506
1507 (4) A pharmacist shall be physically present to directly supervise a pharmacy technician or
1508 pharmacy technician trainee who is entering prescription data into the data processing system.
1509 Each prescription entered into the data processing system shall be verified at the time of data
1510 entry.
1511
1512 (5) All pharmacists while on duty, shall be responsible for complying with all state and federal
1513 laws or rules governing the practice of pharmacy.
1514
1515 (6) A pharmacist shall ensure that the drug is dispensed and delivered safely and accurately
1516 as prescribed. A pharmacist shall ensure the safety and accuracy of the portion of the process
1517 the pharmacist is performing.
1518
1519 (7) Duties, in a satellite pharmacy, that may only be performed by a pharmacist are as follows:
1520
1521 (A) receiving oral prescription drug orders and reducing these orders to writing, either
1522 manually or electronically;
1523
1524 (B) interpreting or clarifying prescription drug orders;
1525

1526 (C) communicating to the patient or patient's agent information about the prescription drug or
1527 device which in the exercise of the pharmacist's professional judgment, the pharmacist deems
1528 significant, as specified in §291.33(c) of this title;

1529
1530 (D) communicating to the patient or the patient's agent on his or her request information
1531 concerning any prescription drugs dispensed to the patient by the pharmacy;

1532
1533 (E) assuring that a reasonable effort is made to obtain, record, and maintain patient
1534 medication records;

1535
1536 (F) interpreting patient medication records and performing drug regimen reviews; and

1537
1538 (G) performing a specific act of drug therapy management for a patient delegated to a
1539 pharmacist by a written protocol from a physician licensed in this state in compliance with the
1540 Medical Practice Act.

1541
1542 (8) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties
1543 listed in paragraph (7) of this subsection. However, a pharmacist may delegate to pharmacy
1544 technicians and pharmacy technician trainees any nonjudgmental technical duty associated with
1545 the preparation and distribution of prescription drugs provided:

1546
1547 (A) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by
1548 pharmacy technicians and pharmacy technician trainees; and

1549
1550 (B) pharmacy technicians and pharmacy technician trainees are under the direct supervision
1551 of and responsible to a pharmacist.

1552
1553 (9) Pharmacy technicians and pharmacy technician trainees, in a satellite pharmacy, may
1554 perform only nonjudgmental technical duties associated with the preparation and distribution of
1555 prescription drugs as follows:

1556
1557 (A) initiating and receiving refill authorization requests;

1558
1559 (B) entering prescription data into a data processing system; and

1560
1561 (C) reconstituting medications.

1562
1563 (10) In a satellite pharmacy, the ratio of pharmacists to pharmacy technicians/pharmacy
1564 technician trainees may be 1:3, provided at least one of the three is a pharmacy technician and
1565 not a pharmacy technician trainee.

1566
1567 (11) All satellite pharmacy personnel shall wear identification tags or badges that bears the
1568 person's name and identifies him or her as a pharmacist, pharmacist intern, pharmacy
1569 technician, or pharmacy technician trainee.

1570
1571 (e) Operational requirements.

1572
1573 (1) Application for permission to provide satellite pharmacy services.

1574
1575 (A) A Class A or Class C pharmacy shall make application to the board to provide satellite
1576 pharmacy services. The application shall contain an affidavit with the notarized signatures of the

1577 pharmacist-in-charge and the person responsible for the on-site operation of the facility where
1578 the satellite pharmacy will be located and include the following:

- 1579
- 1580 (i) the name, address, and license number of the provider pharmacy;
 - 1581
 - 1582 (ii) the name and address of the facility where the satellite pharmacy will be located;
 - 1583
 - 1584 (iii) anticipated date of opening and hours of operation; and
 - 1585
 - 1586 (iv) copy of the lease agreement or if the location of the satellite pharmacy is owned by the
1587 applicant, a notarized statement certifying such location ownership.
 - 1588

1589 (B) Such application shall be resubmitted every two years in conjunction with the application
1590 for renewal of the provider pharmacy's license. The renewal petition shall contain the
1591 documentation required in subparagraph (A) of this paragraph except the notarized signature of
1592 the person responsible for the on-site operation of the facility where the satellite pharmacy will
1593 be located.

1594

1595 (C) Upon approval of the application, the provider pharmacy will be sent a certificate which
1596 must be displayed at the satellite pharmacy.

1597

1598 (2) Notification requirements.

1599

1600 (A) A provider pharmacy shall notify the board in writing within ten days of a change of
1601 location, discontinuance of service, or closure of a satellite pharmacy that is operated by the
1602 pharmacy.

1603

1604 (B) A provider pharmacy shall comply with appropriate federal and state controlled substance
1605 registrations for each satellite pharmacy if controlled substances are maintained at the satellite
1606 pharmacy.

1607

1608 (3) Environment.

1609

1610 (A) The satellite pharmacy shall be arranged in an orderly fashion and kept clean. All required
1611 equipment shall be clean and in good operating condition.

1612

1613 (B) A satellite pharmacy shall contain an area which is suitable for confidential patient
1614 counseling.

1615

1616 (i) Such counseling area shall:

1617

1618 (I) be easily accessible to both patient and pharmacists and not allow patient access to
1619 prescription drugs;

1620

1621 (II) be designed to maintain the confidentiality and privacy of the pharmacist/patient
1622 communication.

1623

1624 (ii) In determining whether the area is suitable for confidential patient counseling and
1625 designed to maintain the confidentiality and privacy of the pharmacist/patient communication,
1626 the board may consider factors such as the following:

1627

- 1628 (I) the proximity of the counseling area to the check-out or cash register area;
1629
1630 (II) the volume of pedestrian traffic in and around the counseling area;
1631
1632 (III) the presence of walls or other barriers between the counseling area and other areas of
1633 the pharmacy; and
1634
1635 (IV) any evidence of confidential information being overheard by persons other than the
1636 patient or patient's agent or the pharmacist or agents of the pharmacist.
1637
1638 (C) The satellite pharmacy shall be properly lighted and ventilated.
1639
1640 (D) The temperature of the satellite pharmacy shall be maintained within a range compatible
1641 with the proper storage of drugs in compliance with the provisions of §291.15 of this title
1642 (relating to storage of drugs). The temperature of the refrigerator shall be maintained within a
1643 range compatible with the proper storage of drugs requiring refrigeration.
1644
1645 (E) Animals, including birds and reptiles, shall not be kept within the pharmacy and in
1646 immediately adjacent areas under the control of the pharmacy. This provision does not apply to
1647 fish in aquariums, guide dogs accompanying disabled persons, or animals for sale to the
1648 general public in a separate area that is inspected by local health jurisdictions.
1649
1650 (4) Security.
1651
1652 (A) A satellite pharmacy shall be under the continuous, physically present supervision of a
1653 pharmacist at all times the satellite pharmacy is open to provide pharmacy services.
1654
1655 (B) The satellite pharmacy shall be enclosed by walls, partitions or other means of floor-to-
1656 ceiling enclosure. In addition, to the security requirements outlined in §291.33(b)(2) of this title,
1657 satellite pharmacies shall have adequate security and procedures to
1658
1659 (i) prohibit unauthorized access;
1660
1661 (ii) comply with federal and state regulations; and
1662
1663 (iii) maintain patient confidentiality.
1664
1665 (C) Access to the satellite pharmacy shall be limited to pharmacists, pharmacy technicians,
1666 and pharmacy technician trainees employed by the provider pharmacy and who are designated
1667 in writing by the pharmacist-in-charge.
1668
1669 (D) The provider pharmacy shall have procedures that specify that prescriptions may only be
1670 delivered to the satellite pharmacy by the provider pharmacy and shall:
1671
1672 (i) be delivered in a sealed container with a list of the prescriptions delivered;
1673
1674 (ii) signed for on receipt by the pharmacist at the satellite pharmacy;
1675
1676 (iii) be checked by personnel designated by the pharmacist-in-charge to verify that the
1677 prescriptions sent by the provider pharmacy were actually received. The designated person who

1678 checks the order shall document the verification by signing and dating the list of prescriptions
1679 delivered.
1680
1681 (5) Prescription dispensing and delivery. A satellite pharmacy shall comply with the
1682 requirements outlines in §291.33(c) of this title with regard to prescription dispensing and
1683 delivery.
1684
1685 (6) Equipment and supplies. A satellite pharmacy shall have the following equipment and
1686 supplies:
1687
1688 (A) typewriter or comparable equipment;
1689
1690 (B) refrigerator, if storing drugs requiring refrigeration;
1691
1692 (C) metric-apothecary weight and measure conversion charts.
1693
1694 (7) Library. A reference library shall be maintained by the satellite pharmacy that includes the
1695 following in hard-copy or electronic format:
1696
1697 (A) current copies of the following:
1698
1699 (i) Texas Pharmacy Act and rules;
1700
1701 (ii) Texas Dangerous Drug Act and rules;
1702
1703 (iii) Texas Controlled Substances Act and rules; and
1704
1705 (iv) Federal Controlled Substances Act and rules (or official publication describing the
1706 requirements of the Federal Controlled Substances Act and rules);
1707
1708 (B) at least one current or updated reference from each of the following categories:
1709
1710 (i) patient information:
1711
1712 (I) United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient);
1713 or
1714
1715 (II) a reference text or information leaflets which provide patient information;
1716
1717 (ii) drug interactions: a reference text on drug interactions, such as Drug Interaction Facts. A
1718 separate reference is not required if other references maintained by the pharmacy contain drug
1719 interaction information including information needed to determine severity or significance of the
1720 interaction and appropriate recommendations or actions to be taken;
1721
1722 (iii) a general information reference text, such as:
1723
1724 (I) Facts and Comparisons with current supplements;
1725
1726 (II) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the
1727 Healthcare Provider);
1728

1729 (III) Clinical Pharmacology;
1730
1731 (IV) American Hospital Formulary Service with current supplements; or
1732
1733 (V) Remington's Pharmaceutical Sciences; and
1734
1735 (C) basic antidote information and the telephone number of the nearest Regional Poison
1736 Control Center.
1737
1738 (f) Records.
1739
1740 (1) Maintenance of records.
1741
1742 (A) Every record required to be kept and §291.34 of this title and under this section shall be;
1743
1744 (i) kept by the provider pharmacy and be available, for at least two years from the date of
1745 such inventory or record, for inspecting and copying by the board or its representative and to
1746 other authorized local, state, or federal law enforcement agencies; and
1747
1748 (ii) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent
1749 of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
1750 format, the requested records must be provided in an electronic format if specifically requested
1751 by the board or its representative. Failure to provide the records set out in this section, either on
1752 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
1753 in violation of the Act.
1754
1755 (B) Records, except when specifically required to be maintained in original or hard-copy form,
1756 may be maintained in an alternative data retention system, such as a data processing system or
1757 direct imaging system provided:
1758
1759 (i) the records maintained in the alternative system contain all of the information required on
1760 the manual record; and
1761
1762 (ii) the data processing system is capable of producing a hard copy of the record upon the
1763 request of the board, its representative, or other authorized local, state, or federal law
1764 enforcement or regulatory agencies.
1765
1766 (C) Prescription drug orders shall be maintained by the provider pharmacy in the manner
1767 required by §291.34(d) or (e) of this title.
1768
1769 (2) Prescriptions.
1770
1771 (A) Prescription drug orders shall meet the requirements of §291.34(b) of this title.
1772
1773 (B) The provider pharmacy must maintain appropriate records to identify the name(s), initials,
1774 or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or
1775 pharmacy technician trainee who performed any processing at the satellite pharmacy.
1776
1777 (C) A provider pharmacy shall keep a record of all prescriptions sent and returned between
1778 the pharmacies separate from the records of the provider pharmacy and from any other satellite
1779 pharmacy's records.

1780
1781 (D) A satellite pharmacy shall keep a record of all prescriptions received and returned
1782 between the pharmacies.

1783
1784
1785 **§291.131 Pharmacies Compounding Non-Sterile Preparations**
1786

1787 (a) Purpose. Pharmacies compounding non-sterile preparations, prepackaging pharmaceutical
1788 products and distributing those products shall comply with all requirements for their specific
1789 license classification and this section. The purpose of this section is to provide standards for
1790 the:

1791
1792 (1) compounding of non-sterile preparations pursuant to a prescription or medication order for
1793 a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-
1794 resident) pharmacies;

1795
1796 (2) compounding, dispensing, and delivery of a reasonable quantity of a compounded non-
1797 sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident)
1798 pharmacies to a practitioner's office for office use by the practitioner;

1799
1800 (3) compounding and distribution of compounded non-sterile preparations by a Class A
1801 (Community) pharmacy for a Class C (Institutional) pharmacy; and

1802
1803 (4) compounding of non-sterile preparations by a Class C (Institutional) pharmacy and the
1804 distribution of the compounded preparations to other Class C (Institutional) pharmacies under
1805 common ownership.

1806
1807 (b) Definitions. In addition to the definitions for specific license classifications, the following
1808 words and terms, when used in this section, shall have the following meanings, unless the
1809 context clearly indicates otherwise.

1810
1811 (1) Beyond-use date--The date or time after which the compounded non-sterile preparation
1812 shall not be stored or transported or begin to be administered to a patient. The beyond-use date
1813 is determined from the date or time when the preparation was compounded.

1814
1815 (2) Component--Any ingredient intended for use in the compounding of a drug preparation,
1816 including those that may not appear in such preparation.

1817
1818 (3) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or
1819 device:

1820
1821 (A) as the result of a practitioner's prescription drug or medication order, based on the
1822 practitioner-patient-pharmacist relationship in the course of professional practice;

1823
1824 (B) for administration to a patient by a practitioner as the result of a practitioner's initiative
1825 based on the practitioner-patient-pharmacist relationship in the course of professional practice;

1826
1827 (C) in anticipation of prescription drug or medication orders based on routine, regularly
1828 observed prescribing patterns; or
1829

1830 (D) for or as an incident to research, teaching, or chemical analysis and not for sale or
1831 dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.
1832
1833 (4) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of
1834 105 degrees F (41 degrees C).
1835
1836 (5) Reasonable quantity--An amount of a compounded drug that:
1837
1838 (A) does not exceed the amount a practitioner anticipates may be used in the practitioner's
1839 office or facility before the beyond use date of the drug;
1840
1841 (B) is reasonable considering the intended use of the compounded drug and the nature of the
1842 practitioner's practice; and
1843
1844 (C) for any practitioner and all practitioners as a whole, is not greater than an amount the
1845 pharmacy is capable of compounding in compliance with pharmaceutical standards for identity,
1846 strength, quality, and purity of the compounded drug that are consistent with United States
1847 Pharmacopoeia guidelines and accreditation practices.
1848
1849 (6) SOPs--Standard operating procedures.
1850
1851 (7) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.
1852
1853 (c) Personnel.
1854
1855 (1) Pharmacist-in-charge. In addition to the responsibilities for the specific class of pharmacy,
1856 the pharmacist-in-charge shall have the responsibility for, at a minimum, the following
1857 concerning non-sterile compounding:
1858
1859 (A) determining that all personnel involved in non-sterile compounding possess the
1860 education, training, and proficiency necessary to properly and safely perform compounding
1861 duties undertaken or supervised;
1862
1863 (B) determining that all personnel involved in non-sterile compounding obtain continuing
1864 education appropriate for the type of compounding done by the personnel;
1865
1866 (C) assuring that the equipment used in compounding is properly maintained;
1867
1868 (D) maintaining an appropriate environment in areas where non-sterile compounding occurs;
1869 and
1870
1871 (E) assuring that effective quality control procedures are developed and followed.
1872
1873 (2) Pharmacists. Special requirements for non-sterile compounding.
1874
1875 (A) All pharmacists engaged in compounding shall:
1876
1877 (i) possess the education, training, and proficiency necessary to properly and safely perform
1878 compounding duties undertaken or supervised; and
1879

1880 (ii) obtain continuing education appropriate for the type of compounding done by the
1881 pharmacist.
1882
1883 (B) A pharmacist shall inspect and approve all components, drug product containers,
1884 closures, labeling, and any other materials involved in the compounding process.
1885
1886 (C) A pharmacist shall review all compounding records for accuracy and conduct in-process
1887 and final checks to ensure that errors have not occurred in the compounding process.
1888
1889 (D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all
1890 equipment used in the compounding process.
1891
1892 (3) Pharmacy technicians and pharmacy technician trainees. All pharmacy technicians and
1893 pharmacy technician trainees engaged in non-sterile compounding shall:
1894
1895 (A) possess the education, training, and proficiency necessary to properly and safely perform
1896 compounding duties undertaken;
1897
1898 (B) obtain continuing education appropriate for the type of compounding done by the
1899 pharmacy technician or pharmacy technician trainee; and
1900
1901 (C) perform compounding duties under the direct supervision of and responsible to a
1902 pharmacist.
1903
1904 (4) Training.
1905
1906 (A) All training activities shall be documented and covered by appropriate SOPs as outlined in
1907 subsection (d)(8)(A) of this section.
1908
1909 (B) All personnel involved in non-sterile compounding shall be well trained and must
1910 participate in continuing relevant training programs.
1911
1912 (d) Operational Standards.
1913
1914 (1) General requirements.
1915
1916 (A) Non-sterile drug preparations may be compounded in licensed pharmacies:
1917
1918 (i) upon presentation of a practitioner's prescription drug or medication order based on a
1919 valid pharmacist/patient/prescriber relationship;
1920
1921 (ii) in anticipation of future prescription drug or medication orders based on routine, regularly
1922 observed prescribing patterns; or
1923
1924 (iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.
1925
1926 (B) Non-sterile compounding in anticipation of future prescription drug or medication orders
1927 must be based upon a history of receiving valid prescriptions issued within an established
1928 pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional
1929 judgment the quantity prepared is stable for the anticipated shelf time.
1930

1931 (i) The pharmacist's professional judgment shall be based on the criteria used to determine
1932 a beyond-use date outlined in paragraph (5)(C) of this subsection.

1933
1934 (ii) Documentation of the criteria used to determine the stability for the anticipated shelf time
1935 must be maintained and be available for inspection.

1936
1937 (iii) Any preparation compounded in anticipation of future prescription drug or medication
1938 orders shall be labeled. Such label shall contain:

1939
1940 (I) name and strength of the compounded preparation or list of the active ingredients and
1941 strengths;

1942
1943 (II) facility's lot number;

1944
1945 (III) beyond-use date as determined by the pharmacist using appropriate documented
1946 criteria as outlined in paragraph (5)(C) of this subsection; and

1947
1948 (IV) quantity or amount in the container.

1949
1950 (C) Commercially available products may be compounded for dispensing to individual
1951 patients provided the following conditions are met:

1952
1953 (i) the commercial product is not reasonably available from normal distribution channels in a
1954 timely manner to meet patient's needs;

1955
1956 (ii) the pharmacy maintains documentation that the product is not reasonably available due
1957 to a drug shortage or unavailability from the manufacturer; and

1958
1959 (iii) the prescribing practitioner has requested that the drug be compounded as described in
1960 subparagraph (D) of this paragraph.

1961
1962 (D) A pharmacy may not compound preparations that are essentially copies of commercially
1963 available products (e.g., the preparation is dispensed in a strength that is only slightly different
1964 from a commercially available product) unless the prescribing practitioner specifically orders the
1965 strength or dosage form and specifies why the patient needs the particular strength or dosage
1966 form of the preparation. The prescribing practitioner shall provide documentation of a patient
1967 specific medical need and the preparation produces a clinically significant therapeutic response
1968 (e.g. the physician requests an alternate product due to hypersensitivity to excipients or
1969 preservative in the FDA-approved product, or the physician requests an effective alternate
1970 dosage form) or if the drug product is not commercially available. The unavailability of such drug
1971 product must be documented prior to compounding. The methodology for documenting
1972 unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered,
1973 discontinued, or out-of-stock items. This documentation must be available in hard-copy or
1974 electronic format for inspection by the board.

1975
1976 (E) A pharmacy may enter into an agreement to compound and dispense
1977 prescription/medication orders for another pharmacy provided the pharmacy complies with the
1978 provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).
1979

1980 (F) Compounding pharmacies/pharmacists may advertise and promote the fact that they
1981 provide non-sterile prescription compounding services, which may include specific drug
1982 products and classes of drugs.

1983
1984 (G) A pharmacy may not compound veterinary preparations for use in food producing animals
1985 except in accordance with federal guidelines.

1986
1987 (H) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's
1988 agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-
1989 date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise
1990 documented. Documentation of beyond-use-dates longer than fourteen days shall be
1991 maintained by the pharmacy electronically or manually and made available to agents of the
1992 board on request. A pharmacist may not add flavoring to an over-the-counter product at the
1993 request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-
1994 the-counter product from the patient's practitioner.

1995
1996 (2) Library. In addition to the library requirements of the pharmacy's specific license
1997 classification, a pharmacy shall maintain a current copy, in hard-copy or electronic format, of
1998 Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations.

1999
2000 (3) Environment.

2001
2002 (A) Pharmacies regularly engaging in compounding shall have a designated and adequate
2003 area for the safe and orderly compounding of non-sterile preparations, including the placement
2004 of equipment and materials. Pharmacies involved in occasional compounding shall prepare an
2005 area prior to each compounding activity which is adequate for safe and orderly compounding.

2006
2007 (B) Only personnel authorized by the responsible pharmacist shall be in the immediate
2008 vicinity of a drug compounding operation.

2009
2010 (C) A sink with hot and cold running water, exclusive of rest room facilities, shall be
2011 accessible to the compounding areas and be maintained in a sanitary condition. Supplies
2012 necessary for adequate washing shall be accessible in the immediate area of the sink and
2013 include:

2014
2015 (i) soap or detergent; and

2016
2017 (ii) air-driers or single-use towels.

2018
2019 (D) If drug products which require special precautions to prevent contamination, such as
2020 penicillin, are involved in a compounding operation, appropriate measures, including dedication
2021 of equipment for such operations or the meticulous cleaning of contaminated equipment prior to
2022 its use for the preparation of other drug products, must be used in order to prevent cross-
2023 contamination.

2024
2025 (4) Equipment and Supplies. The pharmacy shall:

2026
2027 (A) have a Class A prescription balance, or analytical balance and weights which shall be
2028 properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;
2029 and

2030

2031 (B) have equipment and utensils necessary for the proper compounding of prescription drug
2032 or medication orders. Such equipment and utensils used in the compounding process shall be:

- 2033 (i) of appropriate design and capacity, and be operated within designed operational limits;
- 2034
- 2035 (ii) of suitable composition so that surfaces that contact components, in-process material, or
- 2036 drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity,
- 2037 strength, quality, or purity of the drug product beyond the desired result;
- 2038
- 2039 (iii) cleaned and sanitized immediately prior and after to each use; and
- 2040
- 2041 (iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.
- 2042
- 2043

2044 (5) Labeling. In addition to the labeling requirements of the pharmacy's specific license
2045 classification, the label dispensed or distributed pursuant to a prescription drug or medication
2046 order shall contain the following.

- 2047 (A) The generic name(s) or the official name(s) of the principal active ingredient(s) of the
- 2048 compounded preparation.
- 2049
- 2050 (B) A statement that the preparation has been compounded by the pharmacy. (An auxiliary
- 2051 label may be used on the container to meet this requirement).
- 2052
- 2053 (C) A beyond-use date after which the compounded preparation should not be used. The
- 2054 beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning
- 2055 Pharmacy Compounding Non-Sterile Preparations including the following:
- 2056

- 2057 (i) The pharmacist shall consider:
- 2058 (I) physical and chemical properties of active ingredients;
- 2059
- 2060 (II) use of preservatives and/or stabilizing agents;
- 2061
- 2062 (III) dosage form;
- 2063
- 2064 (IV) storage containers and conditions; and
- 2065
- 2066 (V) scientific, laboratory, or reference data from a peer reviewed source and retained in the
- 2067 pharmacy. The reference data should follow the same preparation instructions for combining
- 2068 raw materials and packaged in a container with similar properties.
- 2069

2070 (ii) In the absence of stability information applicable for a specific drug or preparation, the
2071 following maximum beyond-use dates are to be used when the compounded preparation is
2072 packaged in tight, light-resistant containers and stored at controlled room temperatures.

- 2073 (I) Nonaqueous liquids and solid formulations (Where the manufactured drug product is the
- 2074 source of active ingredient): 25% of the time remaining until the product's expiration date or 6
- 2075 months, whichever is earlier.
- 2076
- 2077 (II) Water-containing formulations (Prepared from ingredients in solid form): Not later than
- 2078 14 days when refrigerated between 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit).
- 2079
- 2080
- 2081

2082
2083 (III) All other formulations: Intended duration of therapy or 30 days, whichever is earlier.
2084

2085 (iii) Beyond-use date limits may be exceeded when supported by valid scientific stability
2086 information for the specific compounded preparation.
2087

2088 (6) Written drug information. Written information about the compounded preparation or its
2089 major active ingredient(s) shall be given to the patient at the time of dispensing. A statement
2090 which indicates that the preparation was compounded by the pharmacy must be included in this
2091 written information. If there is no written information available, the patient should be advised that
2092 the drug has been compounded and how to contact a pharmacist, and if appropriate the
2093 prescriber, concerning the drug.
2094

2095 (7) Drugs, components, and materials used in non-sterile compounding.
2096

2097 (A) Drugs used in non-sterile compounding shall be a USP/NF grade substances
2098 manufactured in an FDA-registered facility.
2099

2100 (B) If USP/NF grade substances are not available, or when food, cosmetics, or other
2101 substances are, or must be used, the substance shall be of a chemical grade in one of the
2102 following categories:
2103

2104 (i) Chemically Pure (CP);
2105

2106 (ii) Analytical Reagent (AR); or
2107

2108 (iii) American Chemical Society (ACS); or
2109

2110 (iv) Food Chemical Codex; or
2111

2112 (C) If a drug, component or material is not purchased from a FDA-registered facility, the
2113 pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the
2114 supplier and the pharmacist shall compare the monograph of drugs in a similar class to the
2115 Certificate of Analysis.
2116

2117 (D) A manufactured drug product may be a source of active ingredient. Only manufactured
2118 drugs from containers labeled with a batch control number and a future expiration date are
2119 acceptable as a potential source of active ingredients. When compounding with manufactured
2120 drug products, the pharmacist must consider all ingredients present in the drug product relative
2121 to the intended use of the compounded preparation.
2122

2123 (E) All components shall be stored in properly labeled containers in a clean, dry area, under
2124 proper temperatures.
2125

2126 (F) Drug product containers and closures shall not be reactive, additive, or absorptive so as
2127 to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond
2128 the desired result.
2129

2130 (G) Components, drug product containers, and closures shall be rotated so that the oldest
2131 stock is used first.
2132

2133 (H) Container closure systems shall provide adequate protection against foreseeable external
2134 factors in storage and use that can cause deterioration or contamination of the compounded
2135 drug product.

2136
2137 (I) A pharmacy may not compound a preparation that contains ingredients appearing on a
2138 federal Food and Drug Administration list of drug products withdrawn or removed from the
2139 market for safety reasons.

2140
2141 (8) Compounding process.

2142
2143 (A) All significant procedures performed in the compounding area shall be covered by written
2144 SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the
2145 compounding process. At a minimum, SOPs shall be developed for:

- 2146 (i) the facility;
2147
2148 (ii) equipment;
2149
2150 (iii) personnel;
2151
2152 (iv) preparation evaluation;
2153
2154 (v) quality assurance;
2155
2156 (vi) preparation recall;
2157
2158 (vii) packaging; and
2159
2160 (viii) storage of compounded preparations.

2161
2162 (B) Any compounded preparation with an official monograph in the USP/NF shall be
2163 compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

2164
2165 (C) Any person with an apparent illness or open lesion that may adversely affect the safety or
2166 quality of a drug product being compounded shall be excluded from direct contact with
2167 components, drug product containers, closures, any materials involved in the compounding
2168 process, and drug products until the condition is corrected.

2169
2170 (D) Personnel engaged in the compounding of drug preparations shall wear clean clothing
2171 appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons,
2172 hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect
2173 personnel from chemical exposure and drug preparations from contamination.

2174
2175 (E) At each step of the compounding process, the pharmacist shall ensure that components
2176 used in compounding are accurately weighed, measured, or subdivided as appropriate to
2177 conform to the formula being prepared.

2178
2179 (9) Quality Assurance.

2180
2181

2182 (A) Initial formula validation. Prior to routine compounding of a non-sterile preparation, a
2183 pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding
2184 a product that contains the stated amount of active ingredient(s).

2185
2186 (B) Finished preparation checks. The prescription drug and medication orders, written
2187 compounding procedure, preparation records, and expended materials used to make
2188 compounded non-sterile preparations shall be inspected for accuracy of correct identities and
2189 amounts of ingredients, packaging, labeling, and expected physical appearance before the non-
2190 sterile preparations are dispensed.

2191
2192 (10) Quality Control.

2193
2194 (A) The pharmacy shall follow established quality control procedures to monitor the quality of
2195 compounded drug preparations for uniformity and consistency such as capsule weight
2196 variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures,
2197 pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy
2198 Compounding Non-Sterile Preparations, Chapter 1075, concerning Good Compounding
2199 Practices, and Chapter 1160, concerning Pharmaceutical Calculations in Prescription
2200 Compounding contained in the current USP/NF. Such procedures shall be documented and be
2201 available for inspection.

2202
2203 (B) Compounding procedures that are routinely performed, including batch compounding,
2204 shall be completed and verified according to written procedures. The act of verification of a
2205 compounding procedure involves checking to ensure that calculations, weighing and measuring,
2206 order of mixing, and compounding techniques were appropriate and accurately performed.

2207
2208 (C) Unless otherwise indicated or appropriate, compounded preparations are to be prepared
2209 to ensure that each preparation shall contain not less than 90.0 percent and not more than
2210 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit
2211 weight or volume and not less than 90.0 percent and not more than 110.0 percent of the
2212 theoretically calculated weight or volume per unit of the preparation.

2213
2214 (e) Records.

2215
2216 (1) Maintenance of records. Every record required by this section shall be:

2217
2218 (A) kept by the pharmacy and be available, for at least two years for inspecting and copying
2219 by the board or its representative and to other authorized local, state, or federal law
2220 enforcement agencies; and

2221
2222 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
2223 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
2224 the requested records must be provided in an electronic format. Failure to provide the records
2225 set out in this section, either on site or within 72 hours, constitutes prima facie evidence of
2226 failure to keep and maintain records in violation of the Act.

2227
2228 (2) Compounding records.

2229
2230 (A) Compounding pursuant to patient specific prescription drug or medication orders.
2231 Compounding records for all compounded preparations shall be maintained by the pharmacy

2232 electronically or manually as part of the prescription drug or medication order, formula record,
2233 formula book, or compounding log and shall include:

2234
2235 (i) the date of preparation;

2236
2237 (ii) a complete formula, including methodology and necessary equipment which includes the
2238 brand name(s) of the raw materials, or if no brand name, the generic name(s) and name(s) of
2239 the manufacturer(s) of the raw materials and the quantities of each;

2240
2241 (iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician
2242 trainee performing the compounding;

2243
2244 (iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians
2245 or pharmacy technician trainees and conducting in-process and final checks of compounded
2246 preparations if pharmacy technicians or pharmacy technician trainees perform the compounding
2247 function;

2248
2249 (v) the quantity in units of finished preparations or amount of raw materials;

2250
2251 (vi) the container used and the number of units prepared;

2252
2253 (vii) a reference to the location of the following documentation which may be maintained with
2254 other records, such as quality control records:

2255
2256 (I) the criteria used to determine the beyond-use date; and

2257
2258 (II) documentation of performance of quality control procedures. Documentation of the
2259 performance of quality control procedures is not required if the compounding process is done
2260 pursuant to a patient specific order and involves the mixing of two or more commercially
2261 available oral liquids or commercially available preparations when the final product is intended
2262 for external use.

2263
2264 (B) Compounding records when batch compounding or compounding in anticipation of future
2265 prescription drug or medication orders.

2266
2267 (i) Master work sheet. A master work sheet shall be developed and approved by a
2268 pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work
2269 sheet shall be used as the preparation work sheet from which each batch is prepared and on
2270 which all documentation for that batch occurs. The master work sheet shall contain at a
2271 minimum:

2272
2273 (I) the formula;

2274
2275 (II) the components;

2276
2277 (III) the compounding directions;

2278
2279 (IV) a sample label;

2280
2281 (V) evaluation and testing requirements;

2282

2283 (VI) specific equipment used during preparation; and
2284
2285 (VII) storage requirements.
2286
2287 (ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall
2288 document the following:
2289
2290 (I) identity of all solutions and ingredients and their corresponding amounts,
2291 concentrations, or volumes;
2292
2293 (II) lot number or each component;
2294
2295 (III) component manufacturer/distributor or suitable identifying number;
2296
2297 (IV) container specifications;
2298
2299 (V) unique lot or control number assigned to batch;
2300
2301 (VI) beyond use date of batch-prepared preparations;
2302
2303 (VII) date of preparation;
2304
2305 (VIII) name, initials, or electronic signature of the person(s) involved in the preparation;
2306
2307 (IX) name, initials, or electronic signature of the responsible pharmacist;
2308
2309 (X) finished preparation evaluation and testing specifications, if applicable; and
2310
2311 (XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.
2312
2313 (f) Office Use Compounding and Distribution of Compounded Preparations to Class C
2314 Pharmacies or Veterinarians in Accordance With §563.054 of the Act.
2315
2316 (1) General.
2317
2318 (A) A pharmacy may dispense and deliver a reasonable quantity of a compounded
2319 preparation to a practitioner for office use by the practitioner in accordance with this subsection.
2320
2321 (B) A Class A (Community) pharmacy is not required to register or be licensed under Chapter
2322 431, Health and Safety Code, to distribute non-sterile compounded preparations to a Class C
2323 (Institutional) pharmacy.
2324
2325 (C) A Class C (Institutional) pharmacy is not required to register or be licensed under Chapter
2326 431, Health and Safety Code, to distribute non-sterile compounded preparations that the Class
2327 C pharmacy has compounded for other Class C pharmacies under common ownership.
2328
2329 (D) To dispense and deliver a compounded preparation under this subsection, a pharmacy
2330 must:
2331
2332 (i) verify the source of the raw materials to be used in a compounded drug;
2333

2334 (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing
2335 requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No.
2336 104-191);

2337
2338 (iii) enter into a written agreement with a practitioner for the practitioner's office use of a
2339 compounded preparation;

2340
2341 (iv) comply with all applicable competency and accrediting standards as determined by the
2342 board; and

2343
2344 (v) comply with the provisions of this subsection.

2345
2346 (2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to
2347 practitioners for office use or to another pharmacy shall enter into a written agreement with the
2348 practitioner or pharmacy. The written agreement shall:

2349
2350 (A) address acceptable standards of practice for a compounding pharmacy and a practitioner
2351 and receiving pharmacy that enter into the agreement including a statement that the
2352 compounded preparations may only be administered to the patient and may not be dispensed to
2353 the patient or sold to any other person or entity except as authorized by §563.054 of the Act;

2354
2355 (B) require the practitioner or receiving pharmacy to include on a patient's chart, medication
2356 order, or medication administration record the lot number and beyond-use date of a
2357 compounded preparation administered to a patient; and

2358
2359 (C) describe the scope of services to be performed by the pharmacy and practitioner or
2360 receiving pharmacy, including a statement of the process for:

2361
2362 (i) a patient to report an adverse reaction or submit a complaint; and

2363
2364 (ii) the pharmacy to recall batches of compounded preparations.

2365
2366 (3) Recordkeeping.

2367
2368 (A) Maintenance of Records.

2369
2370 (i) Records of orders and distribution of non-sterile compounded preparations to a
2371 practitioner for office use or to a Class C (Institutional) pharmacy for administration to a patient
2372 shall:

2373
2374 (I) be kept by the pharmacy and be available, for at least two years from the date of the
2375 record, for inspecting and copying by the board or its representative and to other authorized
2376 local, state, or federal law enforcement agencies;

2377
2378 (II) maintained separately from the records of products dispensed pursuant to a
2379 prescription or medication order; and

2380
2381 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
2382 Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in
2383 an electronic format, the requested records must be provided in an electronic format. Failure to

2384 provide the records set out in this subsection, either on site or within 72 hours for whatever
2385 reason, constitutes prima facie evidence of failure to keep and maintain records.

2386
2387 (ii) Records may be maintained in an alternative data retention system, such as a data
2388 processing system or direct imaging system provided the data processing system is capable of
2389 producing a hard copy of the record upon the request of the board, its representative, or other
2390 authorized local, state, or federal law enforcement or regulatory agencies.

2391
2392 (B) Orders. The pharmacy shall maintain a record of all non-sterile compounded preparations
2393 ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient.
2394 The record shall include the following information:

2395
2396 (i) date of the order;

2397
2398 (ii) name, address, and phone number of the practitioner who ordered the preparation and if
2399 applicable, the name, address and phone number of the Class C pharmacy ordering the
2400 preparation; and

2401
2402 (iii) name, strength, and quantity of the preparation ordered.

2403
2404 (C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded
2405 preparations distributed pursuant to an order to a practitioner for office use or by a Class C
2406 pharmacy for administration to a patient. The record shall include the following information:

2407
2408 (i) date the preparation was compounded;

2409
2410 (ii) date the preparation was distributed;

2411
2412 (iii) name, strength and quantity in each container of the preparation;

2413
2414 (iv) pharmacy's lot number;

2415
2416 (v) quantity of containers shipped; and

2417
2418 (vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the
2419 preparation is distributed.

2420
2421 (D) Audit Trail.

2422
2423 (i) The pharmacy shall store the order and distribution records of preparations for all non-
2424 sterile compounded preparations ordered by and or distributed to a practitioner for office use or
2425 by a Class C pharmacy for administration to a patient in such a manner as to be able to provide
2426 a audit trail for all orders and distributions of any of the following during a specified time period.

2427
2428 (I) any strength and dosage form of a preparation (by either brand or generic name or
2429 both);

2430
2431 (II) any ingredient;

2432
2433 (III) any lot number;

2434

2435 (IV) any practitioner;
2436
2437 (V) any facility; and
2438
2439 (VI) any pharmacy, if applicable.
2440
2441 (ii) The audit trail shall contain the following information:
2442
2443 (I) date of order and date of the distribution;
2444
2445 (II) practitioner's name, address, and name of the Class C pharmacy, if applicable;
2446
2447 (III) name, strength and quantity of the preparation in each container of the preparation;
2448
2449 (IV) name and quantity of each active ingredient;
2450
2451 (V) quantity of containers distributed; and
2452
2453 (VI) pharmacy's lot number;
2454
2455 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following
2456 information:
2457
2458 (A) name, address, and phone number of the compounding pharmacy;
2459
2460 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation
2461 is distributed to a veterinarian the statement: "Compounded Preparation";
2462
2463 (C) name and strength of the preparation or list of the active ingredients and strengths;
2464
2465 (D) pharmacy's lot number;
2466
2467 (E) beyond-use date as determined by the pharmacist using appropriate documented criteria;
2468
2469 (F) quantity or amount in the container;
2470
2471 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,
2472 including hazardous drug warning labels where appropriate; and
2473
2474 (H) device-specific instructions, where appropriate.
2475
2476 (g) Recall Procedures.
2477
2478 (1) The pharmacy shall have written procedures for the recall of any compounded non-sterile
2479 preparations provided to a patient, to a practitioner for office use, or a pharmacy for
2480 administration. Written procedures shall include, but not be limited to the requirements as
2481 specified in paragraph (3) of this subsection.
2482
2483 (2) The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded
2484 by the pharmacy upon identification of a potential or confirmed harm to a patient.
2485

- 2486 (3) In the event of a recall, the pharmacist-in-charge shall ensure that:
2487
2488 (A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is
2489 notified, in writing, of the recall;
2490
2491 (B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;
2492
2493 (C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;
2494
2495 (D) if the preparation is distributed for office use, the Texas Department of State Health
2496 Services, Drugs and Medical Devices Group, is notified of the recall, in writing;
2497
2498 (E) the preparation is quarantined; and
2499
2500 (F) the pharmacy keeps a written record of the recall including all actions taken to notify all
2501 parties and steps taken to ensure corrective measures.
2502
2503 (4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if
2504 there is potential for or confirmed harm to a patient.
2505
2506

2507 **§291.133 Pharmacies Compounding Sterile Preparations**

2508

2509 (a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical
2510 products, and distributing those products shall comply with all requirements for their specific
2511 license classification and this section. The purpose of this section is to provide standards for
2512 the:

2513
2514 (1) compounding of sterile preparations pursuant to a prescription or medication order for a
2515 patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-
2516 resident) pharmacies;

2517
2518 (2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile
2519 preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident)
2520 pharmacies to a practitioner's office for office use by the practitioner;

2521
2522 (3) compounding and distribution of compounded sterile preparations by a Class A
2523 (Community) pharmacy for a Class C (Institutional) pharmacy; and

2524
2525 (4) compounding of sterile preparations by a Class C (Institutional) pharmacy and the
2526 distribution of the compounded preparations to other Class C (Institutional) pharmacies under
2527 common ownership.

2528
2529 (b) Definitions. In addition to the definitions for specific license classifications, the following
2530 words and terms, when used in this section, shall have the following meanings, unless the
2531 context clearly indicates otherwise.

2532
2533 (1) ACPE--Accreditation Council for Pharmacy Education.

2534
2535 (2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum
2536 allowable number of particles per cubic meter of air as specified in the International

2537 Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For
2538 example:

2539
2540 (A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than
2541 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles
2542 0.5 microns in diameter per cubic foot of air);

2543
2544 (B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less
2545 than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000
2546 particles 0.5 microns in diameter per cubic foot of air); and

2547
2548 (C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less
2549 than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as
2550 100,000 particles 0.5 microns in diameter per cubic foot of air).

2551
2552 (3) Ancillary supplies--Supplies necessary for the preparation and administration of
2553 compounded sterile preparations.

2554
2555 (4) Anteroom--An ISO Class 8 or better area where personnel may perform hand hygiene and
2556 garbing procedures, staging of components, order entry, labeling, and other high-particulate
2557 generating activities. It is also a transition area that:

2558
2559 (A) provides assurance that pressure relationships are constantly maintained so that air flows
2560 from clean to dirty areas; and

2561
2562 (B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system
2563 to respond to large disturbances.

2564
2565 (5) Aseptic Processing--The technique involving procedures designed to preclude
2566 contamination of drugs, packaging, equipment, or supplies by microorganisms during
2567 preparation.

2568
2569 (6) Automated compounding device--An automated device that compounds, measures, and/or
2570 packages a specified quantity of individual components in a predetermined sequence for a
2571 designated sterile preparation.

2572
2573 (7) Batch--A specific quantity of a drug or other material that is intended to have uniform
2574 character and quality, within specified limits, and is produced during a single preparation cycle.

2575
2576 (8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a
2577 single discrete process, by the same individual(s), carried out during one limited time period.
2578 Batch preparation/compounding does not include the preparation of multiple sterile preparation
2579 units pursuant to patient specific medication orders.

2580
2581 (9) Beyond-use date--The date or time after which the compounded sterile preparation shall
2582 not be stored or transported or begin to be administered to a patient. The beyond-use date is
2583 determined from the date or time the preparation is compounded.

2584
2585 (10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product, and
2586 environmental protection having an open front with inward airflow for personnel protection,

2587 downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air
2588 for environmental protection.

2589
2590 (11) Buffer Area, Buffer or Core Room, Buffer or Clean Room Areas, Buffer Room Area, Buffer
2591 or Clean Area, or Buffer Zone--An ISO Class 7 area where the primary engineering control area
2592 is physically located. Activities that occur in this area include the preparation and staging of
2593 components and supplies used when compounding sterile preparations.

2594
2595 (12) Clean room or controlled area--A room in which the concentration of airborne particles is
2596 controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the
2597 environment are monitored so that a microbial level for air, surface, and personnel gear are not
2598 exceeded for a specified cleanliness class.

2599
2600 (13) Component--Any ingredient intended for use in the compounding of a drug preparation,
2601 including those that may not appear in such preparation.

2602
2603 (14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or
2604 device:

2605
2606 (A) as the result of a practitioner's prescription drug or medication order based on the
2607 practitioner-patient-pharmacist relationship in the course of professional practice;

2608
2609 (B) for administration to a patient by a practitioner as the result of a practitioner's initiative
2610 based on the practitioner-patient-pharmacist relationship in the course of professional practice;

2611
2612 (C) in anticipation of prescription drug or medication orders based on routine, regularly
2613 observed prescribing patterns; or

2614
2615 (D) for or as an incident to research, teaching, or chemical analysis and not for sale or
2616 dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

2617
2618 (15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for
2619 compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic
2620 compounding environment within the isolator throughout the compounding and material transfer
2621 processes. Air exchange into the isolator from the surrounding environment shall not occur
2622 unless it has first passed through a microbial retentive filter (HEPA minimum).

2623
2624 (16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to
2625 provide worker protection from exposure to undesirable levels of airborne drug throughout the
2626 compounding and material transfer processes and to provide an aseptic environment for
2627 compounding sterile preparations. Air exchange with the surrounding environment should not
2628 occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system
2629 capable of containing airborne concentrations of the physical size and state of the drug being
2630 compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator
2631 should be appropriately removed by properly designed building ventilation.

2632
2633 (17) Critical Area--A critical area is an ISO Class 5 environment.

2634
2635 (18) Critical Sites--Sterile ingredients of compounded sterile preparations and locations on
2636 devices and components used to prepare, package, and transfer compounded sterile
2637 preparations that provide opportunity for exposure to contamination.

- 2638
2639 (19) Cytotoxic--A pharmaceutical that has the capability of killing living cells.
2640
2641 (20) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro
2642 reagent, or other similar or related article, including any component part or accessory, that is
2643 required under federal or state law to be ordered or prescribed by a practitioner.
2644
2645 (21) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering
2646 control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first
2647 air.
2648
2649 (22) Disinfectant--A disinfectant is an agent that frees from infection, usually a chemical agent
2650 but sometimes a physical one, and that destroys disease-causing pathogens or other harmful
2651 microorganisms but may not kill bacterial spores. It refers to substances applied to inanimate
2652 objects.
2653
2654 (23) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially
2655 particle free.
2656
2657 (24) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum
2658 of 105 degrees F (41 degrees C).
2659
2660 (25) HVAC--Heating, ventilation, and air conditioning.
2661
2662 (26) Immediate use--A sterile preparation that is not prepared according to USP 797 standards
2663 (i.e. outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for
2664 no longer than one hour after completion of the preparation.
2665
2666 (27) IPA--Isopropyl alcohol (2-propanol).
2667
2668 (28) Media-Fill Test--A media-fill test is used to qualify aseptic technique of compounding
2669 personnel or processes and to ensure that the processes used are able to produce sterile
2670 preparation without microbial contamination. During this test, a microbiological growth medium
2671 such as Soybean--Casein Digest Medium is substituted for the actual drug product to simulate
2672 admixture compounding. The issues to consider in the development of a media-fill test are the
2673 following: media-fill procedures, media selection, fill volume, incubation, time and temperature,
2674 inspection of filled units, documentation, interpretation of results, and possible corrective actions
2675 required.
2676
2677 (29) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for
2678 potential administration only and usually contains antimicrobial preservatives. The beyond-use
2679 date for an opened or entered (e.g., needle-punctured) multiple-dose container with
2680 antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.
2681
2682 (30) Negative Pressure Room--A room that is at a lower pressure compared to adjacent
2683 spaces and, therefore, the net flow of air is into the room.
2684
2685 (31) Office use--The administration of a compounded drug to a patient by a practitioner in the
2686 practitioner's office or by the practitioner in a health care facility or treatment setting, including a
2687 hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or
2688 for administration or provision by a veterinarian in accordance with §563.054 of the Act.

2689
2690 (32) Pharmacy Bulk Package--A container of a sterile preparation for potential use that
2691 contains many single doses. The contents are intended for use in a pharmacy admixture
2692 program and are restricted to the preparation of admixtures for infusion or, through a sterile
2693 transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one
2694 time after constitution with a suitable sterile transfer device or dispensing set, which allows
2695 measured dispensing of the contents. The pharmacy bulk package is to be used only in a
2696 suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

2697
2698 (33) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
2699 manufacturer's original container into unit dose packaging or a multiple dose container for
2700 distribution within a facility licensed as a Class C pharmacy or to other pharmacies under
2701 common ownership for distribution within those facilities. The term as defined does not prohibit
2702 the prepackaging of drug products for use within other pharmacy classes.

2703
2704 (34) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a
2705 licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed
2706 prescriber.

2707
2708 (35) Primary Engineering Control--A device or room that provides an ISO Class 5 environment
2709 for the exposure of critical sites when compounding sterile preparations. Such devices include,
2710 but may not be limited to, laminar airflow workbenches, biological safety cabinets, and
2711 compounding aseptic isolators and compounding aseptic containment isolators.

2712
2713 (36) Product--A product is a commercially manufactured sterile drug or nutrient that has been
2714 evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are
2715 accompanied by full prescribing information, which is commonly known as the FDA-approved
2716 manufacturer's labeling or product package insert.

2717
2718 (37) Positive Control--A quality assurance sample prepared to test positive for microbial
2719 growth.

2720
2721 (38) Positive Pressure Room--A room that is at a higher pressure compared to adjacent
2722 spaces and, therefore, the net airflow is out of the room.

2723
2724 (39) Quality assurance--The set of activities used to ensure that the process used in the
2725 preparation of sterile drug preparations lead to preparations that meet predetermined standards
2726 of quality.

2727
2728 (40) Quality control--The set of testing activities used to determine that the ingredients,
2729 components (e.g., containers), and final compounded sterile preparations prepared meet
2730 predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.

2731
2732 (41) Reasonable quantity--An amount of a compounded drug that:

2733
2734 (A) does not exceed the amount a practitioner anticipates may be used in the practitioner's
2735 office or facility before the beyond use date of the drug;

2736
2737 (B) is reasonable considering the intended use of the compounded drug and the nature of the
2738 practitioner's practice; and

2739

2740 (C) for any practitioner and all practitioners as a whole, is not greater than an amount the
2741 pharmacy is capable of compounding in compliance with pharmaceutical standards for identity,
2742 strength, quality, and purity of the compounded drug that are consistent with United States
2743 Pharmacopoeia guidelines and accreditation practices.

2744
2745 (42) Segregated Compounding Area--A designated space, either a demarcated area or room,
2746 that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less
2747 beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO
2748 Class 5 air quality for preparation of compounded sterile preparations and shall be void of
2749 activities and materials that are extraneous to sterile compounding.

2750
2751 (43) Single-dose container--A container intended for a single use, other than single-dose vials
2752 and single-dose large volume potential solutions. Examples of single-dose containers include
2753 pre-filled syringes, cartridges, and fusion-sealed containers without preservatives.

2754
2755 (44) Single-dose vial--A vial intended for a single use. Exceptions to this definition would be
2756 single dose vials routinely used to compound total potential nutrition (TPN) preparations (e.g.,
2757 sodium chloride, sodium acetate, sodium phosphate, potassium chloride, potassium acetate,
2758 potassium phosphate, calcium gluconate, magnesium sulfate, multivitamin for injection, multi-
2759 trace elements, ascorbic acid, folic acid, heparin, phytonadione, l-carnitine, cysteine, selenium,
2760 injectable zinc).

2761
2762 (45) Single-dose large volume parenteral solution--Large volume parenteral solutions (i.e.,
2763 containers of solution of at least 1000 mL) routinely used for compounding sterile TPN
2764 preparations or for batch compounding (e.g., sterile water for injection (SWFI); 5%, 10%, and
2765 70% dextrose in SWFI; 0.9% sodium chloride; 0.45% sodium chloride; 5% dextrose/0.9%
2766 sodium chloride; 5% dextrose/0.45% sodium chloride).

2767
2768 (46) SOPs--Standard operating procedures.

2769
2770 (47) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or
2771 autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined
2772 sterility assurance level of usually less than 10⁻⁶, i.e., or a probability of less than one in one
2773 million of a non-sterile unit.

2774
2775 (48) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform
2776 manner and at sufficient speed to reproducibly sweep particles away from the critical processing
2777 or testing area.

2778
2779 (49) USP/NF--The current edition of the United States Pharmacopoeia/National Formulary.

2780
2781 (c) Personnel.

2782
2783 (1) Pharmacist-in-charge.

2784
2785 (A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific
2786 license classification of the pharmacy.

2787
2788 (B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the
2789 pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning
2790 the compounding of sterile preparations:

2791
2792 (i) developing a system to ensure that all pharmacy personnel responsible for compounding
2793 and/or supervising the compounding of sterile preparations within the pharmacy receive
2794 appropriate education and training and competency evaluation;
2795
2796 (ii) determining that all personnel involved in compounding sterile preparations obtain
2797 continuing education appropriate for the type of compounding done by the personnel;
2798
2799 (iii) supervising a system to ensure appropriate procurement of drugs and devices and
2800 storage of all pharmaceutical materials including pharmaceuticals, components used in the
2801 compounding of sterile preparations, and drug delivery devices;
2802
2803 (iv) ensuring that the equipment used in compounding is properly maintained;
2804
2805 (v) developing a system for the disposal and distribution of drugs from the pharmacy;
2806
2807 (vi) developing a system for bulk compounding or batch preparation of drugs;
2808
2809 (vii) developing a system for the compounding, sterility assurance, quality assurance, and
2810 quality control of sterile preparations; and
2811
2812 (viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste
2813 in a manner so as not to endanger the public health.
2814
2815 (2) Pharmacists. Special requirements for compounding sterile preparations.
2816
2817 (A) All pharmacists engaged in compounding sterile preparations shall:
2818
2819 (i) possess the education, training, and proficiency necessary to properly and safely perform
2820 compounding duties undertaken or supervised; and
2821
2822 (ii) obtain continuing education appropriate for the type of compounding done by the
2823 pharmacist.
2824
2825 (B) A pharmacist shall inspect and approve all components, drug preparation containers,
2826 closures, labeling, and any other materials involved in the compounding process.
2827
2828 (C) A pharmacist shall review all compounding records for accuracy and conduct in-process
2829 and final checks to ensure that errors have not occurred in the compounding process.
2830
2831 (D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all
2832 equipment used in the compounding process.
2833
2834 (E) A pharmacist shall be accessible at all times to respond to patients' and other health
2835 professionals' questions and needs. Such access may be through a telephone or pager which is
2836 answered 24 hours a day.
2837
2838 (3) Pharmacy technicians and pharmacy technician trainees. Pharmacy technicians and
2839 pharmacy technician trainees may compound sterile preparations provided the pharmacy
2840 technicians and/or pharmacy technician trainees:
2841

2842 (A) have completed the education and training specified in paragraph (4) of this subsection;
2843 and

2844
2845 (B) are supervised by a pharmacist who has completed the training specified in paragraph (4)
2846 of this subsection, conducts in-process and final checks, and affixes his or her initials to the
2847 appropriate quality control records.

2848
2849 (4) Special education, training, and evaluation requirements for pharmacy personnel
2850 compounding or responsible for the direct supervision of pharmacy personnel compounding
2851 sterile preparations.

2852
2853 (A) General.

2854
2855 (i) All pharmacy personnel preparing sterile preparations shall receive didactic and
2856 experiential training and competency evaluation through demonstration, testing (written and
2857 practical) as outlined by the pharmacist-in-charge and described in the policy and procedure or
2858 training manual. Such training shall include instruction and experience in the following areas:

- 2859 (I) aseptic technique;
2860
2861 (II) critical area contamination factors;
2862
2863 (III) environmental monitoring;
2864
2865 (IV) structure and engineering controls related to facilities;
2866
2867 (V) equipment and supplies;
2868
2869 (VI) sterile preparation calculations and terminology;
2870
2871 (VII) sterile preparation compounding documentation;
2872
2873 (VIII) quality assurance procedures;
2874
2875 (IX) aseptic preparation procedures including proper gowning and gloving technique;
2876
2877 (X) handling of cytotoxic and hazardous drugs, if applicable; and
2878
2879 (XI) general conduct in the controlled area.

2880
2881
2882 (ii) The aseptic technique of each person compounding or responsible for the direct
2883 supervision of personnel compounding sterile preparations shall be observed and evaluated as
2884 satisfactory through written and practical tests, and media-fill challenge testing, and such
2885 evaluation documented.

2886
2887 (iii) Although media-fill tests may be incorporated into the experiential portion of a training
2888 program, media-fill tests must be conducted at each pharmacy where an individual compounds
2889 sterile preparations. No preparation intended for patient use shall be compounded by an
2890 individual until the on-site media-fill tests test indicates that the individual can competently
2891 perform aseptic procedures, except that a pharmacist may temporarily compound sterile

2892 preparations and supervise pharmacy technicians compounding sterile preparations without
2893 media-fill tests provided the pharmacist:

2894
2895 (I) has completed a recognized course in an accredited college of pharmacy or a course
2896 sponsored by an ACPE accredited provider which provides 20 hours of instruction and
2897 experience in the areas listed in this subparagraph; and

2898
2899 (II) completes the on-site media-fill tests within seven days of commencing work at the
2900 pharmacy.

2901
2902 (iv) Media-fill tests procedures for assessing the preparation of specific types of sterile
2903 preparations shall be representative of all types of manipulations, products, risk levels, and
2904 batch sizes that personnel preparing that type of sterile preparation are likely to encounter.

2905
2906 (v) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel
2907 through in-service education, training, and media-fill tests to supplement initial training.
2908 Personnel competency shall be evaluated:

2909
2910 (I) during orientation and training prior to the regular performance of those tasks;

2911
2912 (II) whenever the quality assurance program yields an unacceptable result;

2913
2914 (III) whenever unacceptable techniques are observed; and

2915
2916 (IV) at least on an annual basis for low- and medium-risk level compounding, and every six
2917 months for high-risk level compounding.

2918
2919 (B) Pharmacists.

2920
2921 (i) All pharmacists who compound sterile preparations for administration to patients or
2922 supervise pharmacy technicians and pharmacy technician trainees compounding sterile
2923 preparations shall:

2924
2925 (I) complete through a single course, a minimum of 20 hours of instruction and experience
2926 in the areas listed in subparagraph (A) of this paragraph. Such training may be obtained
2927 through:

2928
2929 (-a-) completion of a structured on-the-job didactic and experiential training program at
2930 this pharmacy which provides 20 hours of instruction and experience in the areas listed in
2931 paragraph (1) of this subsection. Such training may not be transferred to another pharmacy
2932 unless the pharmacies are under common ownership and control and use a common training
2933 program; or

2934
2935 (-b-) completion of a recognized course in an accredited college of pharmacy or a course
2936 sponsored by an ACPE accredited provider which provides 20 hours of instruction and
2937 experience in the areas listed in subparagraph (A) of this paragraph.

2938
2939 (II) possess knowledge about:

2940
2941 (-a-) aseptic processing;

2942

2943 (-b-) quality control and quality assurance as related to environmental, component, and
2944 finished preparation release checks and tests;
2945
2946 (-c-) chemical, pharmaceutical, and clinical properties of drugs;
2947
2948 (-d-) container, equipment, and closure system selection; and
2949
2950 (-e-) sterilization techniques.
2951
2952 (ii) The required experiential portion of the training programs specified in this subparagraph
2953 must be supervised by an individual who has already completed training as specified in
2954 subparagraph (B) or (C) of this paragraph.
2955
2956 (C) Pharmacy technicians and pharmacy technician trainees. In addition to specific
2957 qualifications for registration, all pharmacy technicians and pharmacy technician trainees who
2958 compound sterile preparations for administration to patients shall:
2959
2960 (i) have initial training obtained either through completion of:
2961
2962 (I) a single course, a minimum of 40 hours of instruction and experience in the areas listed
2963 in subparagraph (A) of this paragraph. Such training may be obtained through:
2964
2965 (-a-) completion of a structured on-the-job didactic and experiential training program at
2966 this pharmacy which provides 40 hours of instruction and experience in the areas listed in
2967 subparagraph (A) of this paragraph. Such training may not be transferred to another pharmacy
2968 unless the pharmacies are under common ownership and control and use a common training
2969 program; or
2970
2971 (-b-) completion of a course sponsored by an ACPE accredited provider which provides
2972 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph;
2973 or
2974
2975 (II) a training program which is accredited by the American Society of Health-System
2976 Pharmacists. Individuals enrolled in training programs accredited by the American Society of
2977 Health-System Pharmacists may compound sterile preparations in a licensed pharmacy
2978 provided:
2979
2980 (-a-) the compounding occurs only during times the individual is assigned to a pharmacy
2981 as a part of the experiential component of the American Society of Health-System Pharmacists
2982 training program;
2983
2984 (-b-) the individual is under the direct supervision of and responsible to a pharmacist who
2985 has completed training as specified in subparagraph (B) of this paragraph; and
2986
2987 (-c-) the supervising pharmacist conducts in-process and final checks.
2988
2989 (ii) acquire the required experiential portion of the training programs specified in this
2990 subparagraph under the supervision of an individual who has already completed training as
2991 specified in subparagraph (B) or (C) of this paragraph.
2992

2993 (D) Documentation of Training. The pharmacy shall maintain a record on each person who
2994 compounds sterile preparations. The record shall contain, at a minimum, a written record of
2995 initial and in-service training, education, and the results of written and practical testing and
2996 media-fill testing of pharmacy personnel. The record shall be maintained and contain the
2997 following information:

2998 (i) name of the person receiving the training or completing the testing or media-fill tests;

3000 (ii) date(s) of the training, testing, or media-fill challenge testing;

3002 (iii) general description of the topics covered in the training or testing or of the process
3003 validated;

3005 (iv) name of the person supervising the training, testing, or media-fill challenge testing; and

3007 (v) signature or initials of the person receiving the training or completing the testing or
3008 media-fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the
3009 pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or
3010 media-fill challenge testing of personnel.

3012 (d) Operational Standards.

3014 (1) General Requirements.

3016 (A) Sterile preparations may be compounded in licensed pharmacies:

3018 (i) upon presentation of a practitioner's prescription drug or medication order based on a
3019 valid pharmacist/patient/prescriber relationship;

3021 (ii) in anticipation of future prescription drug or medication orders based on routine, regularly
3022 observed prescribing patterns; or

3024 (iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.

3026 (B) Sterile compounding in anticipation of future prescription drug or medication orders must
3027 be based upon a history of receiving valid prescriptions issued within an established
3028 pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional
3029 judgment the quantity prepared is stable for the anticipated shelf time.

3031 (i) The pharmacist's professional judgment shall be based on the criteria used to determine
3032 a beyond-use date outlined in paragraph (5)(G) of this subsection.

3034 (ii) Documentation of the criteria used to determine the stability for the anticipated shelf time
3035 must be maintained and be available for inspection.

3037 (iii) Any preparation compounded in anticipation of future prescription drug or medication
3038 orders shall be labeled. Such label shall contain:

3040 (l) name and strength of the compounded preparation or list of the active ingredients and
3041 strengths;

3044 (II) facility's lot number;
3045
3046 (III) beyond-use date as determined by the pharmacist using appropriate documented
3047 criteria as outlined in paragraph (5)(G) of this subsection;
3048
3049 (IV) quantity or amount in the container;
3050
3051 (V) appropriate ancillary instructions, such as storage instructions or cautionary
3052 statements, including hazardous drug warning labels where appropriate; and
3053
3054 (VI) device-specific instructions, where appropriate.
3055
3056 (C) Commercially available products may be compounded for dispensing to individual
3057 patients provided the following conditions are met:
3058
3059 (i) the commercial product is not reasonably available from normal distribution channels in a
3060 timely manner to meet patient's needs;
3061
3062 (ii) the pharmacy maintains documentation that the product is not reasonably available due
3063 to a drug shortage or unavailability from the manufacturer; and
3064
3065 (iii) the prescribing practitioner has requested that the drug be compounded as described in
3066 subparagraph (D) of this paragraph.
3067
3068 (D) A pharmacy may not compound preparations that are essentially copies of commercially
3069 available products (e.g., the preparation is dispensed in a strength that is only slightly different
3070 from a commercially available product) unless the prescribing practitioner specifically orders the
3071 strength or dosage form and specifies why the patient needs the particular strength or dosage
3072 form of the preparation. The prescribing practitioner shall provide documentation of a patient
3073 specific medical need and the preparation produces a clinically significant therapeutic response
3074 (e.g. the physician requests an alternate product due to hypersensitivity to excipients or
3075 preservative in the FDA-approved product, or the physician requests an effective alternate
3076 dosage form) or if the drug product is not commercially available. The unavailability of such drug
3077 product must be documented prior to compounding. The methodology for documenting
3078 unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered,
3079 discontinued, or out-of-stock items. This documentation must be available in hard-copy or
3080 electronic format for inspection by the board.
3081
3082 (E) A pharmacy may enter into an agreement to compound and dispense
3083 prescription/medication orders for another pharmacy provided the pharmacy complies with the
3084 provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).
3085
3086 (F) Compounding pharmacies/pharmacists may advertise and promote the fact that they
3087 provide sterile prescription compounding services, which may include specific drug preparations
3088 and classes of drugs.
3089
3090 (G) A pharmacy may not compound veterinary preparations for use in food producing animals
3091 except in accordance with federal guidelines.
3092

3093 (2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall
3094 be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF
3095 and as listed below.

3096
3097 (A) Low-risk level compounded sterile preparations.

3098
3099 (i) Low-Risk conditions. Low-risk level (i) compounded sterile preparations are those
3100 compounded under all of the following conditions.

3101
3102 (I) The compounded sterile preparations are compounded with aseptic manipulations
3103 entirely within ISO Class 5 or better air quality using only sterile ingredients, products,
3104 components, and devices.

3105
3106 (II) The compounding involves only transfer, measuring, and mixing manipulations with
3107 closed or sealed packaging systems that are preformed promptly and attentively.

3108
3109 (III) Manipulations are limited to aseptically opening ampuls, penetrating sterile stoppers on
3110 vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile
3111 administration devices and packages of other sterile products.

3112
3113 (IV) For a low-risk preparation, in the absence of direct sterility testing results or
3114 appropriate information sources that justify different limits, the storage periods may not exceed
3115 the following periods: before administration, 48 hours at controlled room temperature, for not
3116 more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen state at
3117 minus 20 degrees Celsius or colder). For delayed activation device systems, the storage period
3118 begins when the device is activated.

3119
3120 (ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the
3121 following.

3122
3123 (I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials
3124 using sterile syringes with sterile needles, other administration devices, and other sterile
3125 containers. The solution content of ampules shall be passed through a sterile filter to remove
3126 any glass particles.

3127
3128 (II) Manually measuring and mixing no more than three manufactured products to
3129 compound drug admixtures.

3130
3131 (B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date.
3132 Low-risk level compounded sterile preparations are those compounded pursuant to a
3133 physician's order for a specific patient under all of the following conditions.

3134
3135
3136 (i) The compounded sterile preparations are compounded in compounding aseptic isolator
3137 or compounding aseptic containment isolator that does not meet the requirements described in
3138 paragraph (5)(A)(ii)(II) of this subsection relating to Low and Medium Risk Preparations or the
3139 compounded sterile preparations are compounded in laminar airflow workbench or a biological
3140 safety cabinet that cannot be located within an ISO Class 7 buffer area.

3141

3142 (ii) The primary engineering control device is located in a segregated compounding area
3143 restricted to sterile compounding activities that minimizes the risk of contamination of the
3144 compounded sterile preparation.

3145
3146 (iii) The segregated compounding area shall not be in a location that has unsealed windows
3147 or doors that connect to the outdoors, or that is adjacent to construction sites, warehouses, or
3148 food preparation.

3149
3150 (iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this
3151 subparagraph, administration of such compounded sterile preparations must commence within
3152 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is
3153 less.

3154
3155 (C) Medium-risk level compounded sterile preparations.

3156
3157 (i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those
3158 compounded aseptically under low-risk conditions and one or more of the following conditions
3159 exists.

3160
3161 (I) Multiple individual or small doses of sterile products are combined or pooled to prepare
3162 a compounded sterile preparation that will be administered either to multiple patients or to one
3163 patient on multiple occasions.

3164
3165 (II) The compounding process includes complex aseptic manipulations other than the
3166 single-volume transfer.

3167
3168 (III) The compounding process requires unusually long duration, such as that required to
3169 complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous
3170 immunoglobulin or other intravenous protein products).

3171
3172 (IV) The compounded sterile preparations do not contain broad spectrum bacteriostatic
3173 substances and they are administered over several days (e.g., an externally worn infusion
3174 device).

3175
3176 (V) For a medium-risk preparation, in the absence of direct sterility testing results or
3177 appropriate information sources that justify different limits the beyond use dates may not exceed
3178 the following time periods: before administration, the compounded sterile preparations are
3179 properly stored and are exposed for not more than 30 hours at controlled room temperature, for
3180 not more than 9 days at a cold temperature, and for 45 days in solid frozen state at minus 20
3181 degrees Celsius or colder.

3182
3183 (ii) Examples of medium-risk compounding. Examples of medium-risk compounding include
3184 the following.

3185
3186 (I) Compounding of total parenteral nutrition fluids using a manual or automated device
3187 during which there are multiple injections, detachments, and attachments of nutrient source
3188 products to the device or machine to deliver all nutritional components to a final sterile
3189 container.

3190
3191 (II) Filling of reservoirs of injection and infusion devices with multiple sterile drug products
3192 and evacuations of air from those reservoirs before the filled device is dispensed.

3193
3194 (III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug
3195 solutions that will be administered over several days at ambient temperatures between 25 and
3196 40 degrees Celsius (77 and 104 degrees Fahrenheit).
3197
3198 (IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or
3199 product.
3200
3201 (D) High-risk level compounded sterile preparations.
3202
3203 (i) High-risk Conditions. High-risk level compounded sterile preparations are those
3204 compounded under any of the following conditions.
3205
3206 (I) Non-sterile ingredients, including manufactured products are incorporated or a non-
3207 sterile device is employed before terminal sterilization.
3208
3209 (II) Sterile ingredients, components, devices, and mixtures are exposed to air quality
3210 inferior to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened
3211 or partially used packages of manufactured sterile products that lack antimicrobial
3212 preservatives.
3213
3214 (III) Non-sterile preparations are exposed no more than 6 hours before being sterilized.
3215
3216 (IV) It is assumed, and not verified by examination of labeling and documentation from
3217 suppliers or by direct determination, that the chemical purity and content strength of ingredients
3218 meet their original or compendial specifications in unopened or in opened packages of bulk
3219 ingredients.
3220
3221 (V) For a high-risk preparation, in the absence of direct sterility testing results or
3222 appropriate information sources that justify different limits, the storage periods cannot exceed
3223 the following time periods: before administration, the compounded sterile preparations are
3224 properly stored and are exposed for not more than 24 hours at controlled room temperature, for
3225 not more than 3 days at a cold temperature, and for 45 days in solid frozen state at minus 20
3226 degrees or colder.
3227
3228 (VI) All non-sterile measuring, mixing, and purifying equipment is rinsed thoroughly with
3229 sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for
3230 high-risk compounding while assuring cleanliness. All high-risk compounded sterile aqueous
3231 solutions subjected to terminal sterilization are passed through a filter with a nominal porosity
3232 not larger than 1.2 micron preceding or during filling into their final containers to remove
3233 particulate matter. Sterilization of high-risk level compounded sterile preparations by filtration
3234 shall be performed entirely within an ISO Class 5 or superior air quality environment.
3235
3236 (ii) Examples of high-risk compounding. Examples of high-risk compounding include the
3237 following.
3238
3239 (I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally
3240 sterilized.
3241
3242 (II) Exposing the sterile ingredients and components used to prepare and package
3243 compounded sterile preparations to room air quality worse than ISO Class 5.

3244
3245
3246
3247
3248
3249
3250
3251
3252
3253
3254
3255
3256
3257
3258
3259
3260
3261
3262
3263
3264
3265
3266
3267
3268
3269
3270
3271
3272
3273
3274
3275
3276
3277
3278
3279
3280
3281
3282
3283
3284
3285
3286
3287
3288
3289
3290
3291
3292
3293

(III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed.

(IV) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

(3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or immediate patient care, such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the compounded sterile preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Compounded sterile preparations are exempted from the requirements described in this paragraph for low-risk, medium-risk, and high-risk level compounded sterile preparations when all of the following criteria are met.

(A) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile non-hazardous commercial drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution.

(B) Unless required for the preparation, the preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.

(C) Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.

(D) When the compounded sterile preparations is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 1-hour beyond-use time and date.

(E) If administration has not begun within one hour following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use.

(F) Cytotoxic drugs shall not be prepared as immediate use compounded sterile preparations.

(4) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:

(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;

(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs; and

3294 (C) the United States Pharmacopeia/National Formulary or the USP Pharmacist's
3295 Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding--Sterile
3296 Preparations.
3297
3298 (5) Environment. Compounding facilities shall be physically designed and environmentally
3299 controlled to minimize airborne contamination of critical sites.
3300
3301 (A) Low and Medium Risk Preparations.
3302
3303 (i) A pharmacy that prepares low- and medium-risk preparations shall have a clean
3304 room/controlled area for the compounding of sterile preparations that is constructed to minimize
3305 the opportunities for particulate and microbial contamination. The clean room/controlled area
3306 shall:
3307
3308 (I) be clean, well lit, and of sufficient size to support sterile compounding activities;
3309
3310 (II) be used only for the compounding of sterile preparations;
3311
3312 (III) be designed such that hand sanitizing and gowning occurs outside the buffer area but
3313 allows hands-free access by compounding personnel to the buffer room/area;
3314
3315 (IV) have non-porous and washable floors or floor covering to enable regular disinfection;
3316
3317 (V) be ventilated in a manner to avoid disruption from the HVAC system and room cross-
3318 drafts;
3319
3320 (VI) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth,
3321 impervious, free from cracks and crevices (e.g., coved), nonshedding and resistant to damage
3322 by disinfectant agents;
3323
3324 (VII) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;
3325
3326 (VIII) have drugs and supplies stored on shelving areas above the floor to permit adequate
3327 floor cleaning;
3328
3329 (IX) contain only the appropriate compounding supplies and not be used for bulk storage
3330 for supplies and materials. Objects that shed particles shall not be brought into the controlled
3331 area;
3332
3333 (X) contain an anteroom/ante-zone that provides at least an ISO class 8 air quality and
3334 may contain a sink that enables hands-free use with a closed system of soap dispensing to
3335 minimize the risk of extrinsic contamination; and
3336
3337 (XI) contain a buffer zone or buffer room designed to maintain at least ISO Class 7
3338 conditions. The following is applicable for the buffer area.
3339
3340 (-a-) There shall be some demarcation designation that delineates the anteroom or area
3341 from the buffer area. The demarcation shall be such that it does not create conditions that could
3342 adversely affect the cleanliness of the area.
3343

3344 (-b-) The buffer area shall be segregated from surrounding, unclassified spaces to reduce
3345 the risk of contaminants being blown, dragged, or otherwise introduced into the filtered
3346 unidirectional airflow environment, and this segregation should be continuously monitored.

3347
3348 (-c-) A buffer zone that is not physically separated from the anteroom shall employ the
3349 principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--
3350 Sterile Preparations, of the USP/NF, with limited access to personnel.

3351
3352 (-d-) The buffer area shall not contain sources of water (i.e., sinks) or floor drains.

3353
3354 (ii) The pharmacy shall prepare sterile pharmaceuticals in a primary engineering control
3355 device, such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator,
3356 compounding aseptic containment isolator which is capable of maintaining at least ISO Class 5
3357 conditions during normal activity.

3358
3359 (I) The primary engineering control shall:

3360
3361 (-a-) be located in the buffer area or room and placed in the buffer area in a manner as to
3362 avoid conditions that could adversely affect its operation such as strong air currents from
3363 opened doors, personnel traffic, or air streams from the heating, ventilating and air condition
3364 system.

3365
3366 (-b-) be certified by an independent contractor according to the International Organization
3367 of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for
3368 operational efficiency at least every six months and when it is relocated, in accordance with the
3369 manufacturer's specifications; and

3370
3371 (-c-) have pre-filters inspected periodically and replaced as needed, in accordance with
3372 written policies and procedures and the manufacturer's specification, and the inspection and/or
3373 replacement date documented.

3374
3375 (II) The compounding aseptic isolator or compounding aseptic containment isolator must
3376 be placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions.

3377
3378 (-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during
3379 dynamic operating conditions including transferring ingredients, components, and devices into
3380 and out of the isolator and during preparation of compounded sterile preparations.

3381
3382 (-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical
3383 exposure site must maintain ISO Class 5 levels during compounding operations.

3384
3385 (-c-) The pharmacy shall maintain documentation from the manufacturer that the isolator
3386 meets this standard when located in worse than ISO Class 7 environments.

3387
3388 (B) High-risk Preparations. In addition to the requirements in subparagraph (A) of this
3389 paragraph, when high-risk preparations are compounded, the primary engineering control shall
3390 be located in a buffer room that provides a physical separation, through the use of walls, doors
3391 and pass-throughs and has a minimum differential positive pressure of 0.02 to 0.05 inches
3392 water column.

3393

3394 (C) Automated compounding device. If automated compounding devices are used, the
3395 pharmacy shall have a method to calibrate and verify the accuracy of automated compounding
3396 devices used in aseptic processing and document the calibration and verification on a routine
3397 basis, based on the manufacturer's recommendations.
3398

3399 (D) Cytotoxic drugs. If the preparation is cytotoxic, the following is also applicable.
3400

3401 (i) General.
3402

3403 (I) All personnel involved in the compounding of cytotoxic products shall wear appropriate
3404 protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or
3405 dedicated shoes, and appropriate gloving.
3406

3407 (II) Appropriate safety and containment techniques for compounding cytotoxic drugs shall
3408 be used in conjunction with aseptic techniques required for preparing sterile preparations.
3409

3410 (III) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal
3411 requirements.
3412

3413 (IV) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions
3414 inside and outside, and distributed in a manner to minimize patient contact with cytotoxic
3415 agents.
3416

3417 (ii) Primary engineering control device. Cytotoxic drugs shall be prepared in a Class II or III
3418 vertical flow biological safety cabinet or compounding aseptic containment isolator located in an
3419 ISO Class 7 area that is physically separated from other preparation areas. The area for
3420 preparation of sterile chemotherapeutic preparations shall:
3421

3422 (I) have not less than 0.01 inches water column negative pressure to the adjacent positive
3423 pressure ISO Class 7 or better anteaarea; and
3424

3425 (II) have a pressure indicator that can be readily monitored for correct room pressurization.
3426

3427 (iii) Facilities that prepare a low volume of cytotoxic drugs. Pharmacies that prepare a low
3428 volume of cytotoxic drugs, are not required to comply with the provisions of clause (ii) of this
3429 subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g.,
3430 closed-system vial transfer device within a BSC or CACI that is located in a non-negative
3431 pressure room).
3432

3433 (E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and
3434 disinfecting practices and frequencies apply to direct and contiguous compounding areas, which
3435 include ISO Class 5 compounding areas for exposure of critical sites as well as buffer rooms,
3436 anterooms, and ante-areas.
3437

3438 (i) The pharmacist-in-charge is responsible for developing written procedures for cleaning
3439 and disinfecting the direct and contiguous compounding areas and assuring the procedures are
3440 followed.
3441

3442 (ii) These procedures shall be conducted prior to and after each work shift (at a minimum of
3443 every 12 hours while the pharmacy is open) and when there are spills or environmental quality
3444 breaches.

3445
3446 (iii) Before compounding is performed, all items are removed from the direct and contiguous
3447 compounding areas and all surfaces are cleaned of loose material and residue from spills,
3448 followed by an application of a residue-free disinfecting agent (e.g., IPA), that is left on for a time
3449 sufficient to exert its antimicrobial effect.

3450
3451 (iv) Work surfaces near the direct and contiguous compounding areas in the buffer or clean
3452 area are cleaned of loose material and residue from spills, followed by an application of a
3453 residue-free disinfecting agent that is left on for a time sufficient to exert its antimicrobial effect.

3454
3455 (v) Floors in the buffer or clean area are cleaned by mopping at least once daily when no
3456 aseptic operations are in progress preceding from the buffer or clean room area to the anteroom
3457 area.

3458
3459 (vi) In the anteroom area, walls, ceilings, and shelving shall be cleaned monthly.

3460
3461 (vii) Supplies and equipment removed from shipping cartons must be wiped with a
3462 disinfecting agent, such as IPA. However, if supplies are received in sealed pouches, the
3463 pouches may be removed as the supplies are introduced into the buffer or clean area without
3464 the need to disinfect the individual supply items. No shipping or other external cartons may be
3465 taken into the buffer or clean area.

3466
3467 (viii) Storage shelving, emptied of all supplies, walls, and ceilings are cleaned and
3468 disinfected at planned intervals, monthly, if not more frequently.

3469
3470 (F) Security requirements. The pharmacy may authorize personnel to gain access to that
3471 area of the pharmacy containing dispensed sterile preparations, in the absence of the
3472 pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the
3473 pharmacy allows such after-hours access, the area containing the dispensed sterile
3474 pharmaceuticals shall be an enclosed and lockable area separate from the area containing
3475 undispensed prescription drugs. A list of the authorized personnel having such access shall be
3476 in the pharmacy's policy and procedure manual.

3477
3478 (G) Storage requirements and beyond-use dating.

3479
3480 (i) Storage requirements. All drugs shall be stored at the proper temperature and conditions,
3481 as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

3482
3483 (ii) Beyond-use dating.

3484
3485 (I) Beyond-use dates for compounded sterile preparations shall be assigned based on
3486 professional experience, which shall include careful interpretation of appropriate information
3487 sources for the same or similar formulations.

3488
3489 (II) Beyond-use dates for compounded sterile preparations that are prepared strictly in
3490 accordance with manufacturers' product labeling must be those specified in that labeling, or
3491 from appropriate literature sources or direct testing.

3492
3493 (III) Beyond-use dates for compounded sterile preparations that lack justification from
3494 either appropriate literature sources or by direct testing evidence must be assigned as
3495 described in Chapter 797, Pharmaceutical Compounding--Sterile Preparations of the USP/NF.

3496
3497 (6) Equipment and supplies. Pharmacies compounding sterile preparations shall have the
3498 following equipment and supplies:
3499
3500 (A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure
3501 that proper storage requirements are met, if sterile pharmaceuticals are stored in the
3502 refrigerator;
3503
3504 (B) a calibrated system or device to monitor the temperature where bulk chemicals are
3505 stored;
3506
3507 (C) if applicable, a Class A prescription balance, or analytical balance and weights. Such
3508 balance shall be properly maintained and subject to periodic inspection by the Texas State
3509 Board of Pharmacy;
3510
3511 (D) equipment and utensils necessary for the proper compounding of sterile preparations.
3512 Such equipment and utensils used in the compounding process shall be:
3513
3514 (i) of appropriate design, appropriate capacity, and be operated within designed operational
3515 limits;
3516
3517 (ii) of suitable composition so that surfaces that contact components, in-process material, or
3518 drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity,
3519 strength, quality, or purity of the drug preparation beyond the desired result;
3520
3521 (iii) cleaned and sanitized immediately prior to and after each use; and
3522
3523 (iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;
3524
3525 (E) appropriate disposal containers for used needles, syringes, etc., and if applicable,
3526 hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;
3527
3528 (F) appropriate packaging or delivery containers to maintain proper storage conditions for
3529 sterile preparations;
3530
3531 (G) infusion devices, if applicable; and
3532
3533 (H) all necessary supplies, including:
3534
3535 (i) disposable needles, syringes, and other supplies for aseptic mixing;
3536
3537 (ii) disinfectant cleaning solutions;
3538
3539 (iii) hand washing agents with bactericidal action;
3540
3541 (iv) disposable, lint free towels or wipes;
3542
3543 (v) appropriate filters and filtration equipment;
3544
3545 (vi) cytotoxic spill kits, if applicable; and
3546

3547 (vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as
3548 applicable.
3549
3550 (7) Labeling.
3551
3552 (A) Prescription drug or medication orders. In addition to the labeling requirements for the
3553 pharmacy's specific license classification, the label dispensed or distributed pursuant to a
3554 prescription drug or medication order shall contain the following.
3555
3556 (i) The generic name(s) or the official name(s) of the principal active ingredient(s) of the
3557 compounded sterile preparation.
3558
3559 (ii) For outpatient prescription orders only, a statement that the compounded sterile
3560 preparation has been compounded by the pharmacy. (An auxiliary label may be used on the
3561 container to meet this requirement).
3562
3563 (iii) A beyond-use date. The beyond-use date shall be determined as outlined in Chapter
3564 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (4) of this
3565 subsection.
3566
3567 (B) Batch. If the sterile pharmaceutical is compounded in a batch, the following shall also be
3568 included on the batch label.
3569
3570 (i) unique lot number assigned to the batch;
3571
3572 (ii) quantity;
3573
3574 (iii) appropriate ancillary instructions, such as storage instructions or cautionary statements,
3575 including hazardous drug warning labels where appropriate; and
3576
3577 (iv) device-specific instructions, where appropriate.
3578
3579 (C) Pharmacy bulk package. The label of a pharmacy bulk package shall:
3580
3581 (i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"
3582
3583 (ii) contain or refer to information on proper techniques to help ensure safe use of the
3584 preparation; and
3585
3586 (iii) bear a statement limiting the time frame in which the container may be used once it has
3587 been entered, provided it is held under the labeled storage conditions.
3588
3589 (8) Written drug information for prescription drug orders only. Written information about the
3590 compounded preparation or its major active ingredient(s) shall be given to the patient at the time
3591 of dispensing a prescription drug order. A statement which indicates that the preparation was
3592 compounded by the pharmacy must be included in this written information. If there is no written
3593 information available, the patient shall be advised that the drug has been compounded and how
3594 to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.
3595

3596 (9) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the
3597 pharmacy's specific license classification, the following requirements for sterile preparations
3598 compounded pursuant to prescription drug orders must be met.
3599

3600 (A) Primary provider. There shall be a designated physician primarily responsible for the
3601 patient's medical care. There shall be a clear understanding between the physician, the patient,
3602 and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the
3603 monitoring of the patient. This shall be documented in the patient medication record (PMR).
3604

3605 (B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient
3606 and/or patient's caregiver receives information regarding drugs and their safe and appropriate
3607 use, including instruction when applicable, regarding:
3608

3609 (i) appropriate disposition of hazardous solutions and ancillary supplies;
3610

3611 (ii) proper disposition of controlled substances in the home;
3612

3613 (iii) self-administration of drugs, where appropriate;
3614

3615 (iv) emergency procedures, including how to contact an appropriate individual in the event of
3616 problems or emergencies related to drug therapy; and
3617

3618 (v) if the patient or patient's caregiver prepares sterile preparations in the home, the
3619 following additional information shall be provided:
3620

3621 (I) safeguards against microbial contamination, including aseptic techniques for
3622 compounding intravenous admixtures and aseptic techniques for injecting additives to premixed
3623 intravenous solutions;
3624

3625 (II) appropriate storage methods, including storage durations for sterile pharmaceuticals
3626 and expirations of self-mixed solutions;
3627

3628 (III) handling and disposition of premixed and self-mixed intravenous admixtures; and
3629

3630 (IV) proper disposition of intravenous admixture compounding supplies such as syringes,
3631 vials, ampules, and intravenous solution containers.
3632

3633 (C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be
3634 established and maintained throughout the patient's course of therapy. This shall be
3635 documented in the patient's medication record (PMR).
3636

3637 (D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:
3638

3639 (i) the patient's response to drug therapy is monitored and conveyed to the appropriate
3640 health care provider; and
3641

3642 (ii) the first dose of any new drug therapy is administered in the presence of an individual
3643 qualified to monitor for and respond to adverse drug reactions.
3644

3645 (10) Drugs, components, and materials used in sterile compounding.
3646

3647 (A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in
3648 an FDA-registered facility.

3649
3650 (B) If USP/NF grade substances are not available shall be of a chemical grade in one of the
3651 following categories:

3652
3653 (i) Chemically Pure (CP);

3654
3655 (ii) Analytical Reagent (AR);

3656
3657 (iii) American Chemical Society (ACS); or

3658
3659 (iv) Food Chemical Codex.

3660
3661 (C) If a drug, component or material is not purchased from a FDA-registered facility, the
3662 pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the
3663 supplier and the pharmacist shall compare the monograph of drugs in a similar class to the
3664 Certificate of Analysis.

3665
3666 (D) All components shall:

3667
3668 (i) be manufactured in an FDA-registered facility; or

3669
3670 (ii) in the professional judgment of the pharmacist, be of high quality and obtained from
3671 acceptable and reliable alternative sources; and

3672
3673 (iii) stored in properly labeled containers in a clean, dry area, under proper temperatures.

3674
3675 (E) Drug product containers and closures shall not be reactive, additive, or absorptive so as
3676 to alter the safety, identity, strength, quality, or purity of the compounded drug preparation
3677 beyond the desired result.

3678
3679 (F) Components, drug preparation containers, and closures shall be rotated so that the oldest
3680 stock is used first.

3681
3682 (G) Container closure systems shall provide adequate protection against foreseeable external
3683 factors in storage and use that can cause deterioration or contamination of the compounded
3684 drug preparation.

3685
3686 (H) A pharmacy may not compound a preparation that contains ingredients appearing on a
3687 federal Food and Drug Administration list of drug products withdrawn or removed from the
3688 market for safety reasons.

3689
3690 (11) Compounding process.

3691
3692 (A) Standard operating procedures (SOPs). All significant procedures performed in the
3693 compounding area shall be covered by written SOPs designed to ensure accountability,
3694 accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall
3695 be developed for:

3696
3697 (i) the facility;

3698
3699 (ii) equipment;
3700
3701 (iii) personnel;
3702
3703 (iv) preparation evaluation;
3704
3705 (v) quality assurance;
3706
3707 (vi) preparation recall;
3708
3709 (vii) packaging; and
3710
3711 (viii) storage of compounded sterile preparations.
3712
3713 (B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be
3714 compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.
3715
3716 (C) Personnel Cleansing and Garbing.
3717
3718 (i) Any person with an apparent illness or open lesion that may adversely affect the safety or
3719 quality of a drug preparation being compounded shall be excluded from direct contact with
3720 components, drug preparation containers, closures, any materials involved in the compounding
3721 process, and drug products until the condition is corrected.
3722
3723 (ii) Before entering the clean area, compounding personnel must remove the following:
3724
3725 (I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters,
3726 vests);
3727
3728 (II) all cosmetics, because they shed flakes and particles; and
3729
3730 (III) all hand, wrist, and other body jewelry.
3731
3732 (iii) The wearing of artificial nails or extenders is prohibited while working in the sterile
3733 compounding environment.
3734
3735 (iv) Personnel must don personal protective equipment and perform hand hygiene in an
3736 order that proceeds from the dirtiest to the cleanest activities as follows:
3737
3738 (I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers,
3739 head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye
3740 shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents.
3741
3742 (II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face
3743 masks, personnel shall perform a hand hygiene procedure by removing debris from underneath
3744 fingernails using a nail cleaner under running warm water followed by vigorous hand washing.
3745 Personnel shall begin washing arms at the hands and continue washing to elbows for at least
3746 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in
3747 the anteroom/ante-area.
3748

3749 (III) After completion of hand washing, personnel shall don clean non-shedding gowns with
3750 sleeves that fit snugly around the wrists.

3751
3752 (IV) Gloves that form a continuous barrier with the gown shall be the last item donned
3753 before compounding begins.

3754
3755 (V) Gloves, either those which are sterile or have been disinfected by applying 70% IPA or
3756 appropriate disinfectant to all contact surface areas and allowed to dry, that form a continuous
3757 barrier with the gown shall be the last item donned before compounding begins. Routine
3758 application of 70% IPA shall occur throughout the compounding day and whenever nonsterile
3759 surfaces are touched.

3760
3761 (VI) When compounding personnel must temporarily exit the ISO Class 7 environment
3762 during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the
3763 ISO Class 8 anteroom/ante-area, to be re-donned during that same work shift only. However,
3764 shoe covers, hair and facial hair covers, face mask/eye shield, and gloves must be replaced
3765 with new ones before re-entering the ISO Class 7 clean environment along with performing
3766 proper hand hygiene.

3767
3768 (D) At each step of the compounding process, the pharmacist shall ensure that components
3769 used in compounding are accurately weighed, measured, or subdivided as appropriate to
3770 conform to the formula being prepared.

3771
3772 (12) Quality Assurance.

3773
3774 (A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a
3775 pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding
3776 a product that is sterile and that contains the stated amount of active ingredient(s).

3777
3778 (i) Low risk preparations.

3779
3780 (I) Quality assurance practices include, but are not limited to the following:

3781
3782 (-a-) Routine disinfection and air quality testing of the direct compounding environment to
3783 minimize microbial surface contamination and maintain ISO Class 5 air quality.

3784
3785 (-b-) Visual confirmation that compounding personnel are properly donning and wearing
3786 appropriate items and types of protective garments and goggles.

3787
3788 (-c-) Review of all orders and packages of ingredients to ensure that the correct identity
3789 and amounts of ingredients were compounded.

3790
3791 (-d-) Visual inspection of compounded sterile preparations to ensure the absence of
3792 particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy
3793 and thoroughness of labeling.

3794
3795 (II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at
3796 least annually by each person authorized to compound in a low-risk level under conditions that
3797 closely simulate the most challenging or stressful conditions encountered during compounding
3798 of low-risk level sterile produce. Once begun, this test is completed without interruption within an
3799 ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean--

3800 Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented
3801 needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-
3802 milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically
3803 affixed to the rubber closures on the three filled vials. The vials are incubated within a range of
3804 20 - 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or
3805 before 14 days. The media-fill test must include a positive-control sample.

3806

3807 (ii) Medium risk preparations.

3808

3809 (I) Quality assurance procedures for medium-risk level compounded sterile preparations
3810 include all those for low-risk level compounded sterile preparations, as well as a more
3811 challenging media-fill test passed annually, or more frequently.

3812

3813 (II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at
3814 least annually under conditions that closely simulate the most challenging or stressful conditions
3815 encountered during compounding. This test is completed without interruption within an ISO
3816 Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean--Casein Digest
3817 Medium are aseptically transferred by gravity through separate tubing sets into separate
3818 evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile
3819 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter
3820 aliquots of medium from one container to the other container in the pair. For example, after a 5-
3821 milliliter aliquot from the first container is added to the second container in the pair, the second
3822 container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the
3823 first container in the pair. The first container is then agitated for 10 seconds, and the next 5-
3824 milliliter aliquot is transferred from it back to the second container in the pair. Following the two
3825 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each
3826 container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile
3827 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the
3828 rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35
3829 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before
3830 14 days. The media-fill test must include a positive-control sample.

3831

3832 (iii) High risk preparations.

3833

3834 (I) Procedures for high-risk level compounded sterile preparations include all those for low-
3835 risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk
3836 level compounding is performed twice a year by each person authorized to compound high-risk
3837 level compounded sterile preparations.

3838

3839 (II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by
3840 Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the
3841 most challenging or stressful conditions encountered when compounding high-risk level
3842 compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile
3843 preparations are not required unless they are prepared in batches of more than 25 units. This
3844 test is completed without interruption in the following sequence:

3845

3846 (-a-) Dissolve 3 grams of nonsterile commercially available Soybean--Casein Digest
3847 Medium in 100 milliliters of non-bacteriostatic water to make a 3% nonsterile solution.

3848

3849 (-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes.
3850 Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the

3851 positive controls to generate exponential microbial growth, which is indicated by visible turbidity
3852 upon incubation.

3853
3854 (-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron
3855 porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each
3856 syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials.
3857 Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at
3858 20 to 35 degrees Celsius. Inspect for microbial growth over 14 days as described in Chapter
3859 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.

3860
3861 (B) Finished preparation release checks and tests.

3862
3863 (i) High-risk level compounded sterile preparations. All high-risk level compounded sterile
3864 preparations that are prepared in groups of more than 25 identical individual single-dose
3865 packages (such as ampuls, bags, syringes, and vials), or in multiple dose vials for
3866 administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius
3867 (36 - 46 degrees Fahrenheit) and longer than six hours at warmer than 8 degrees Celsius (46
3868 degrees Fahrenheit) before they are sterilized shall be tested to ensure they are sterile and do
3869 not contain excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the
3870 USP/NF.

3871
3872 (ii) All compounded sterile preparations that are intended to be solutions must be visually
3873 examined for the presence of particulate matter and not administered or dispensed when such
3874 matter is observed.

3875
3876 (iii) The prescription drug and medication orders, written compounding procedure,
3877 preparation records, and expended materials used to make compounded sterile preparations at
3878 all contamination risk levels shall be inspected for accuracy of correct identities and amounts of
3879 ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical
3880 appearance before they are administered or dispensed.

3881
3882 (13) Quality control.

3883
3884 (A) Quality control procedures. The pharmacy shall follow established quality control
3885 procedures to monitor the compounding environment and quality of compounded drug
3886 preparations for conformity with the quality indicators established for the preparation. When
3887 developing these procedures, pharmacy personnel shall consider the provisions of Chapter 797,
3888 Pharmaceutical Compounding--Sterile Preparations, Chapter 1075, Good Compounding
3889 Practices, and Chapter 1160, Pharmaceutical Calculations in Prescription Compounding of the
3890 current USP/NF. Such procedures shall be documented and be available for inspection.

3891
3892 (B) Verification of compounding accuracy and sterility.

3893
3894 (i) The accuracy of identities, concentrations, amounts, and purities of ingredients in
3895 compounded sterile preparations shall be confirmed by reviewing labels on packages, observing
3896 and documenting correct measurements with approved and correctly standardized devices, and
3897 reviewing information in labeling and certificates of analysis provided by suppliers.

3898
3899 (ii) If the correct identify, purity, strength, and sterility of ingredients and components of
3900 compounded sterile preparations cannot be confirmed such ingredients and components shall
3901 be discarded immediately.

3902
3903 (iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration
3904 dates, when the drug substances are stable indefinitely in their commercial packages under
3905 labeled storage conditions, such ingredients may gain or lose moisture during storage and use
3906 and shall require testing to determine the correct amount to weigh for accurate content of active
3907 chemical moieties in compounded sterile preparations.

3908
3909 (e) Records.

3910
3911 (1) Maintenance of records. Every record required under this section must be:

3912
3913 (A) kept by the provider pharmacy and be available, for at least two years for inspecting and
3914 copying by the board or its representative and to other authorized local, state, or federal law
3915 enforcement agencies; and

3916
3917 (B) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of
3918 the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
3919 format, the requested records must be provided in an electronic format. Failure to provide the
3920 records set out in this section, either on site or within 72 hours, constitutes prima facie evidence
3921 of failure to keep and maintain records in violation of the Act.

3922
3923 (2) Compounding records.

3924
3925 (A) Compounding pursuant to patient specific prescription drug orders. Compounding records
3926 for all compounded pharmaceuticals shall be maintained by the pharmacy electronically or
3927 manually as part of the prescription drug or medication order, formula record, formula book, or
3928 compounding log and shall include:

3929
3930 (i) the date of preparation;

3931
3932 (ii) a complete formula, including methodology and necessary equipment which includes the
3933 brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name
3934 and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of
3935 each;

3936
3937 (iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician
3938 trainee performing the compounding;

3939
3940 (iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians
3941 or pharmacy technician trainees and conducting in-process and finals checks of compounded
3942 pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the
3943 compounding function;

3944
3945 (v) the quantity in units of finished products or amount of raw materials;

3946
3947 (vi) the container used and the number of units prepared; and

3948
3949 (vii) a reference to the location of the following documentation which may be maintained with
3950 other records, such as quality control records:

3951
3952 (l) the criteria used to determine the beyond-use date; and

3953
3954 (II) documentation of performance of quality control procedures.
3955
3956 (B) Compounding records when batch compounding or compounding in anticipation of future
3957 prescription drug or medication orders.
3958
3959 (i) Master work sheet. A master work sheet shall be developed and approved by a
3960 pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work
3961 sheet shall be used as the preparation work sheet from which each batch is prepared and on
3962 which all documentation for that batch occurs. The master work sheet shall contain at a
3963 minimum:
3964
3965 (I) the formula;
3966
3967 (II) the components;
3968
3969 (III) the compounding directions;
3970
3971 (IV) a sample label;
3972
3973 (V) evaluation and testing requirements;
3974
3975 (VI) specific equipment used during preparation; and
3976
3977 (VII) storage requirements.
3978
3979 (ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall
3980 document the following:
3981
3982 (I) identity of all solutions and ingredients and their corresponding amounts,
3983 concentrations, or volumes;
3984
3985 (II) lot number for each component;
3986
3987 (III) component manufacturer/distributor or suitable identifying number;
3988
3989 (IV) container specifications (e.g., syringe, pump cassette);
3990
3991 (V) unique lot or control number assigned to batch;
3992
3993 (VI) expiration date of batch-prepared preparations;
3994
3995 (VII) date of preparation;
3996
3997 (VIII) name, initials, or electronic signature of the person(s) involved in the preparation;
3998
3999 (IX) name, initials, or electronic signature of the responsible pharmacist;
4000
4001 (X) finished preparation evaluation and testing specifications, if applicable; and
4002
4003 (XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.

4004
4005 (f) Office Use Compounding and Distribution of Compounded Preparations to Class C
4006 Pharmacies or Veterinarians in Accordance with §563.054 of the Act.
4007
4008 (1) General.
4009
4010 (A) A pharmacy may dispense and deliver a reasonable quantity of a compounded
4011 preparation to a practitioner for office use by the practitioner in accordance with this subsection.
4012
4013 (B) A Class A (Community) pharmacy is not required to register or be licensed under Chapter
4014 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C
4015 (Institutional) pharmacy.
4016
4017 (C) A Class C (Institutional) pharmacy is not required to register or be licensed under Chapter
4018 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C
4019 pharmacy has compounded for other Class C pharmacies under common ownership.
4020
4021 (D) To dispense and deliver a compounded preparation under this subsection, a pharmacy
4022 must:
4023
4024 (i) verify the source of the raw materials to be used in a compounded drug;
4025
4026 (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing
4027 requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No.
4028 104-191);
4029
4030 (iii) enter into a written agreement with a practitioner for the practitioner's office use of a
4031 compounded preparation;
4032
4033 (iv) comply with all applicable competency and accrediting standards as determined by the
4034 board; and
4035
4036 (v) comply with the provisions of this subsection.
4037
4038 (2) Written Agreement. A pharmacy that provides sterile compounded preparations to
4039 practitioners for office use or to another pharmacy shall enter into a written agreement with the
4040 practitioner or pharmacy. The written agreement shall:
4041
4042 (A) address acceptable standards of practice for a compounding pharmacy and a practitioner
4043 and receiving pharmacy that enter into the agreement including a statement that the
4044 compounded drugs may only be administered to the patient and may not be dispensed to the
4045 patient or sold to any other person or entity except as authorized by §563.054 of the Act;
4046
4047 (B) require the practitioner or receiving pharmacy to include on a patient's chart, medication
4048 order or medication administration record the lot number and beyond-use date of a
4049 compounded preparation administered to a patient;
4050
4051 (C) describe the scope of services to be performed by the pharmacy and practitioner or
4052 receiving pharmacy, including a statement of the process for:
4053
4054 (i) a patient to report an adverse reaction or submit a complaint; and

4055
4056 (ii) the pharmacy to recall batches of compounded preparations.
4057
4058 (3) Recordkeeping.
4059
4060 (A) Maintenance of Records.
4061
4062 (i) Records of orders and distribution of sterile compounded preparations to a practitioner for
4063 office use or to a Class C pharmacy for administration to a patient shall:
4064
4065 (I) be kept by the pharmacy and be available, for at least two years from the date of the
4066 record, for inspecting and copying by the board or its representative and to other authorized
4067 local, state, or federal law enforcement agencies;
4068
4069 (II) maintained separately from the records of products dispensed pursuant to a
4070 prescription or medication order; and
4071
4072 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
4073 Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in
4074 an electronic format, the requested records must be provided in an electronic format. Failure to
4075 provide the records set out in this subsection, either on site or within 72 hours for whatever
4076 reason, constitutes prima facie evidence of failure to keep and maintain records.
4077
4078 (ii) Records may be maintained in an alternative data retention system, such as a data
4079 processing system or direct imaging system provided the data processing system is capable of
4080 producing a hard copy of the record upon the request of the board, its representative, or other
4081 authorized local, state, or federal law enforcement or regulatory agencies.
4082
4083 (B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations
4084 ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient.
4085 The record shall include the following information:
4086
4087 (i) date of the order;
4088
4089 (ii) name, address, and phone number of the practitioner who ordered the preparation and if
4090 applicable, the name, address and phone number of the Class C Pharmacy ordering the
4091 preparation; and
4092
4093 (iii) name, strength, and quantity of the preparation ordered.
4094
4095 (C) Distributions. The pharmacy shall maintain a record of all sterile compounded
4096 preparations distributed pursuant to an order to a practitioner for office use or by a Class C
4097 pharmacy for administration to a patient. The record shall include the following information:
4098
4099 (i) date the preparation was compounded;
4100
4101 (ii) date the preparation was distributed;
4102
4103 (iii) name, strength and quantity in each container of the preparation;
4104
4105 (iv) pharmacy's lot number;

4106
4107 (v) quantity of containers shipped; and
4108
4109 (vi) name, address, and phone number of the practitioner or Class C Pharmacy to whom the
4110 preparation is distributed.
4111
4112 (D) Audit Trail.
4113
4114 (i) The pharmacy shall store the order and distribution records of preparations for all sterile
4115 compounded preparations ordered by and or distributed to a practitioner for office use or by a
4116 Class C pharmacy for administration to a patient in such a manner as to be able to provide a
4117 audit trail for all orders and distributions of any of the following during a specified time period.
4118
4119 (I) any strength and dosage form of a preparation (by either brand or generic name or
4120 both);
4121
4122 (II) any ingredient;
4123
4124 (III) any lot number;
4125
4126 (IV) any practitioner;
4127
4128 (V) any facility; and
4129
4130 (VI) any pharmacy, if applicable.
4131
4132 (ii) The audit trail shall contain the following information:
4133
4134 (I) date of order and date of the distribution;
4135
4136 (II) practitioner's name, address, and name of the Class C pharmacy, if applicable;
4137
4138 (III) name, strength and quantity of the preparation in each container of the preparation;
4139
4140 (IV) name and quantity of each active ingredient;
4141
4142 (V) quantity of containers distributed; and
4143
4144 (VI) pharmacy's lot number;
4145
4146 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following
4147 information:
4148
4149 (A) name, address, and phone number of the compounding pharmacy;
4150
4151 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation
4152 is distributed to a veterinarian the statement: "Compounded Preparation";
4153
4154 (C) name and strength of the preparation or list of the active ingredients and strengths;
4155
4156 (D) pharmacy's lot number;

4157
4158 (E) beyond-use date as determined by the pharmacist using appropriate documented criteria;
4159
4160 (F) quantity or amount in the container;
4161
4162 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,
4163 including hazardous drug warning labels where appropriate; and
4164
4165 (H) device-specific instructions, where appropriate.
4166
4167 (g) Recall Procedures.
4168
4169 (1) The pharmacy shall have written procedures for the recall of any compounded sterile
4170 preparation provided to a patient, to a practitioner for office use, or a pharmacy for
4171 administration. Written procedures shall include, but not be limited to the requirements as
4172 specified in paragraph (3) of this subsection.
4173
4174 (2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by
4175 the pharmacy upon identification of a potential or confirmed harm to a patient.
4176
4177 (3) In the event of a recall, the pharmacist-in-charge shall ensure that:
4178
4179 (A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is
4180 notified, in writing, of the recall;
4181
4182 (B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;
4183
4184 (C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;
4185
4186 (D) if the preparation is distributed for office use, the Texas Department of State Health
4187 Services, Drugs and Medical Devices Group, is notified of the recall, in writing;
4188
4189 (E) the preparation is quarantined; and
4190
4191 (F) the pharmacy keeps a written record of the recall including all actions taken to notify all
4192 parties and steps taken to ensure corrective measures.
4193
4194 (4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if
4195 there is potential for or confirmed harm to a patient.